NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

January 15-16, 2025

HILTON GARDEN INN
7830 S LAS VEGAS BLVD
LAS VEGAS, NV

Zoom
https://zoom.us/j/5886256671
Meeting ID: 5886256671

Please do not remove the book from the meeting room.

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

Date Posted: December 30, 2024

THIRD AMENDED AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, January 15, 2025, at 9:00 am. The meeting will continue Thursday, January 16, 2025, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Blvd
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Please Note:

In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety, and welfare of the public.

Please note that items on this agenda may be taken out of order, two or more agenda items may be combined for consideration, and/or items may be removed from the agenda or delayed for discussion at any time.

The Board may convene in closed session pursuant to NRS 241.030 to consider the character, alleged misconduct, professional competence or physical or mental health of any person named on this agenda.

The Board will take public comment on any matters within their jurisdiction, control, or advisory power. Public comments may be limited to three minutes per person. Public comment may also be submitted to the Board at teambc@pharmacy.nv.gov.

The Board may refuse to consider public comment related to a contested case pursuant to NRS 233B.126 until the Board has rendered a decision in the contested case.

1. Call to Order and Roll Call – Establishment of Quorum

2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the December 4-5, 2024, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

   A. 365 DME, LLC – Pitrsford, MI
   B. Cabretta, LLC – St. George, UT
   C. Dr. Micro Labd, LLC – Houston, TX
   D. Eastern Medtech – Walpole, MA
   E. R.A. Fischer Company – Moorpark, CA

   4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

   Background Check Not Required by Law.

   4.2.1 Publicly Traded (NAC 639.593(6)(a))

   F. Cardinal Health 200, LLC – Sacramento, CA

   4.2.2 Publicly Traded and VAWD-Accredited (NAC 639.593(6)(a) and (c))

   4.2.3 Publicly Traded and Manufacturer (NAC 639.593(6)(a) and (d))

   G. G1 Therapeutics, Inc – Research Triangle Park, NC
   H. Nuvation Bio Inc – Burlington, MA

   4.2.4 Publicly Traded, VAWD-Accredited, and Manufacturer (NAC 639.593(6)(a), (c), and (d))

   4.2.5 VAWD-Accredited (NAC 639.593(6)(c))

   I. Drugzone Pharmaceuticals, Inc – Nanuet, NY
   J. Specialty Care Distribution – Ontario, CA
   K. VET4U, LLC – Clay City, NY

4.2.6 Manufacturer (NAC 639.593(6)(d))

L. Bausch & Lomb, Inc – Lynchburg, VA
M. Bausch & Lomb, Inc – Woodruff, SC
N. Boehringer Ingelheim Pharmaceuticals, Inc – Ridgefield, CT
O. Bora Pharmaceuticals Injectable Inc – Baltimore, MD
P. DiaSorin Inc – Stillwater, MN
Q. Exeltis USA, Inc – Florham Park, NJ
R. Fronseca Biosciences, LLC – Long Beach Township, NJ
S. Leo Pharma Inc – Madison, NJ
T. Marius Pharmaceuticals, Inc – Raleigh, NC
U. Matheson Tri-Gas, Inc – Vernon, CA
V. Neurotech Pharmaceuticals, Inc – Cumberland, RI
W. Novadoz Pharmaceuticals, LLC – Piscataway, NJ
X. Societal CDMO Gainesville, LLC – Gainesville, GA
Y. Valinor Pharma, LLC – Bedminster, NJ

4.2.7 VAWD-Accredited and Manufacturer (NAC 639.593(6)(c) and (d))

Z. Braeburn Inc. – Plymouth Meeting, PA

4.2.8 Distributor for Single Manufacturer (NAC 639.593(6)(e))

AA. Advanz Pharma (US) Corp – Bannockburn, IL
BB. Coloplast Corp – Burnsville, MN
CC. Intuvie LLC – Natick, MA
DD. The Flume Catheter Company, Inc – Salt Lake City, UT

4.2.9 <u>Background checks completed in compliance with NRS 639.500.</u>

EE. 365 DME, LLC – Pittsford, MI
FF. Advanced Medical Sales, Inc – San Clemente, CA
GG. Drive DeVilbiss Healthcare – Palmeto, GA
HH. Drive DeVilbiss Healthcare – South Brunswick, NJ
II. Durbin USA – Garner, NC
JJ. Nippon Express U.S.A., Inc – Grapevine, TX

4.3 Application for Out-of-State Outsourcing Facility (NRS 639.100) – Non-Appearance (**FOR POSSIBLE ACTION**)

KK. Asteria Health – Birmingham, AL

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-Appearance **(FOR POSSIBLE ACTION)**

LL. Allivet – Las Vegas, NV
MM. Culinary Pharmacy – North Las Vegas, NV

4.5 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

NN. AeQuita Pharmacy – Kirkland, WA
OO. Kroger Specialty Infusion – Torrance, CA
PP. Northwest Compounders – Beaverton, OR
QQ. PharmaLogic Salt Lake City, LLC – Salt Lake City, UT
RR. Precision Compounding Pharmacy and Wellness – Bellmore, NY
SS. RLS (USA), Inc. – Wooddale, IL
TT. Saveway Compounding Pharmacy, LLC – Newark, DE
UU. Wedgewood Pharmacy – Novato, CA

4.6 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-Appearance – **(FOR POSSIBLE ACTION)**

VV. Allivet – Fishers, IN
WW. Allivet – Miami Lakes, FL
XX. AmeriPharma Medbox – Laguna Hills, CA
YY. BioPlus Specialty Pharmacy Services, LLC – Durham, NC
ZZ. CarelonRx Pharmacy, Inc – Mason, OH
AAA. Go MD Pharmacy, LLC – Memphis, TN
BBB. Health Care Medical Infusion Specialties – Ridgeland, MS
CCC. LifeMD Pharmacy Services, LLC – Lancaster, PA
DDD. NPS Pharmacy Direct – Nashville, TN
EEE. Pathway Pharmacy, Inc – Ocala, FL
FFF. Santa Cruz Rx Texas Pharmacy – Weatherford, TX

4.7 Application for Out-of-State Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

4.8 Request to Engage in The Practice of Pharmacy at A Site Other Than a Licensed Pharmacy – Non-Appearance **(FOR POSSIBLE ACTION)**

4.9 Recommended Denial of Registration/Licensure Due to Material Omissions on Application – Non-Appearance **(FOR POSSIBLE ACTION)**

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Susan Bell (21-084-CS-S)
B. Sherman Washington (19-243-CS-A and 21-104-CS-N)
C. Samuel Yu (22-185-CS-A-S)
D. Mee Han (22-185-CS-B-S)
E. Jeffrey Gross (22-417-CS-S)
F. Walmart Pharmacy #10-5070 (22-537-PH-S)
G. William Joseph Hergenroeder (22-537-RPH-A-S)

H. Hermon Habtom Bariagabr (22-537-RPH-B-S)
I. Safe Chain Solutions (24-356-WH-O)
J. John Katzen (24-389-CS-S)
K. Jon Siems (23-449-CS-S and 24-390-CS-S)
L. Alexander Lee (22-217-CS-S)
M. Jesse Bradberry (23-490-PTT-S)
N. Stuart Berliner (24-161-RPH-S)
O. Medical N Mobility (24-219-MP-S)
P. Orthopedic Motion, Inc. (24-281-MP-S)

6. Appeal hearing pursuant to NRS 639.2895(2) **(FOR POSSIBLE ACTION)**

    A. Nova Specialty Pharmacy

7. Review of compliance with Order Amending Stipulation and Order entered October 16, 2024, in Case No. 23-063-PH-S **(FOR POSSIBLE ACTION)**

    A. American Wellness Pharmacy (23-063-PH-S)

8. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

    A. Advance Pharma – Las Vegas, NV
    B. Family Primary and Specialty Care Pharmacy – Las Vegas, NV
    C. Health Works Pharmacy – Las Vegas, NV
    D. Las Vegas Radiopharmacy, Inc – Las Vegas, NV
    E. Lumis Pharmacy – Las Vegas, NV
    F. QHR Pharmacy #3 LLC – Las Vegas, NV

9. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

    A. Allergychoices Pharmacy – Onalaska, WI
    B. Albertsons Central Fill Pharmacy Phoenix – Phoenix, AZ
    C. Drugco Health – Roanoke Rapids, NC

10. Application for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLE ACTION)**

    A. Paragon Implant Company, LLC – Las Vegas, NV – Background Check Not Required
    B. Stericycle, Inc – McCarran, NV – Background Check Not Required

11. Application for Pharmaceutical Technician in Training Registration (NAC 639.240) – Appearance. (**FOR POSSIBLE ACTION)**

    A. Amanda Moreno
    B. Lucy Magaly Cruz

12. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    A. John Vennochi
    B. Sherman Washington
    C. Victor Jimenez Bonuel

13. Application for Controlled Substance Registration Renewal (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    A. Dana Marks
    B. Steven Huerta

14. Request for Presentation by Nevada Governor's Council on Developmental Disabilities Regarding Potential Solutions with Obtaining Approvals for Durable Medical Equipment (DME) in the State of Nevada – Department of Health and Human Service Staff (NRS 241.020(3)(d)(2) – **(FOR POSSIBLE ACTION)**

15. Discussion and Determination Related to NRS 639.120, the Administration of an Exam on the Law by the Board (NRS 241.020(3)(d)(2) - **(FOR POSSIBLE ACTION)**

◈ PUBLIC HEARING ◈

Thursday, January 16, 2025 – 9:00 am

16. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION)**

    A. **Amendment to Nevada Administrative Code ("NAC").** The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise. (LCB File No. R113-24)

17. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

18. Executive Secretary Report:

    A. Financial Report
    B. Issuance of Temporary Licenses and Registrations
    C. Change of Address Business List
    D. Meetings with Other Health Care Regulatory Boards
    E. Licensing Activities Report
    F. Citations & Fines issued pursuant to NRS 632.2895
    G. Legislative update

19. Date and Location of Next Scheduled Board Meeting:

March 5-6, 2025 – Las Vegas, NV

20. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

21. Adjournment

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Darlene Nases at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Darlene Nases at (775) 850-1440, email teambc@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

Continuing Education credit of 4 hours, including 1 hour of law, will be given per day of in-person Board meeting attendance pursuant to NAC 639.330(1)(b)(2). You are required to attend the board meeting for a full day to receive CE credit including the law credit.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to NRS 241.020 (4).

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

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MINUTES

December 4-5, 2024

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, December 4, 2024, at 9:00 am. The meeting will continue Thursday, December 5, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Blvd.
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Board Members Present:

Helen Park	Krystal Freitas	Richard Tomasso	Adam Porath
Jade Jacobo	Chanyis Taylor	Anna Carr	

Board Staff Present:

David Wuest	Gregory Zunino	Brett Kandt	Monica Moazez
Darlene Nases	Erin Miller	Dena McClish	Jessette Phaynarikone
Joe Dodge	Darla Zarley	John Castaldo	Ken Scheuber
Leo Basch	Todd Weiss	Daniel Leon	Yenh Long

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

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David Wuest, Executive Secretary, stated that this Board Meeting is being held over Zoom and is in compliance with the Open Meeting Laws for Nevada.

1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. Board members were present, and a quorum was established.

2. Public Comment December 4, 2024, 9:07 AM

There was no public comment.

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of October 16-17, 2024, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the October 2024 Board Meeting minutes.

Second: Adam Porath

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

A. ABC Home Medical Supply, Inc – Richardson, TX
B. EBI, LLC – Parsipanny, NJ
C. Firefly Supply, LLC – West Columbia, SC
D. Nationwide Medical, Inc – Calabasas, CA
E. Verse Medical – New York, NY

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

Background Check Not Required by Law.

4.2.1 Publicly Traded (NAC 639.593(6)(a))

F. AstraZeneca Pharmaceuticals LP – Wilmington, DE
G. PTC Therapeutics US, Inc – Warren, NJ

4.2.2 Publicly Traded and VAWD-Accredited (NAC 639.593(6)(a) and (c))

H. McKesseon Medical Surgical, Inc – Suwanee, GA

4.2.3 Publicly Traded and Manufacturer (NAC 639.593(6)(a) and (d))

I. Arvinas Operations, Inc – New Haven, CT
J. BioMimetic Therapeutics, LLC – Franklin, TN
K. GE Medical System Information Technologies, Inc – El Paso, TX
L. ImmunoGen, Inc – Waltham, MA

4.2.4 Publicly Traded, VAWD-Accredited, and Manufacturer (NAC 39.593(6)(a), (c), and (d))

M. VAWD-Accredited (NAC 639.593(6)(c))
N. Auburn Pharmaceutical, LLC – Rochester Hills, MI
O. Auburn Pharmaceutical, LLC – Salt Lake City, UT
P. Smith Drug Company – Paragould, AR

4.2.5 Manufacturer (NAC 639.593(6)(d))

Q. 3B Medical, Inc – Sarasota, FL
R. Amici Pharma, Inc – Melville, NY
S. Coupler LLC – Westchester, PA
T. Everest Life Sciences, LLC – Plainsboro, NJ
U. Fresenius Kabi USA, LLC – Grand Island, NY
V. Genetech USA, Inc – South San Francisco, CA
W. Gramercy Extremity Orthopedics - TX
X. Innogenix, LLC – Amityville, NY
Y. Keystone Industries – Myerstown, PA
Z. Mylan Institutional, Inc – Greensboro, NC
AA. Sintetica US LLC – Princeton, NJ
BB. Teleflex, LLC – Chelmsford, MA
CC. Utopic Pharmaceuticals Inc. – Coral Springs, FL
DD. Waylis Therapeutics, LLC – Rahway, NJ
EE. ZO Skin Health, Inc – Irvine, CA

4.2.6 VAWD-Accredited and Manufacturer (NAC 639.593(6)(c) and (d))

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FF. INO Therapeutics, LLC – Coppell, TX
GG. INO Therapeutics, LLC – West Sacramento, CA

4.2.7 Distributor for Single Manufacturer (NAC 639.593(6)(e))

4.2.8 Background checks completed in compliance with NRS 639.500.

HH. Advanced Medical Sales, Inc – Ponder, TX
II. Cardio Partners, Inc – Greenwood, IN
II. Fisher BioService, Inc – Germantown, MD
JJ. One Beat CPR Learning Center, LLC – Miramar, FL
KK. Pharmaceutical Trade Service, Inc – Ocean Springs, MS
LL. SMC Returns Corp. – Hewlett, NY

4.3 Application for Nevada Pharmacy License (NRS 639.230) – Non-Appearance **(FOR POSSIBLE ACTION)**

MM. ER at South Summerlin an Extension of Summerlin Hospital – Las Vegas, NV
NN. LV Pharmacy and Medical Supplies – Las Vegas, NV
OO. Southwest Medical Specialties Pharmacy – Las Vegas, NV
PP. St. Mary Pharmacy – Henderson, NV
QQ. The Medicine Shoppe LTC Pharmacy – Las Vegas, NV

4.4 Application for Out-of-State Outsourcing Facility (NRS 639.100) – Non-Appearance (**FOR POSSIBLE ACTION**)

RR. Wedgewood Pharmacy, LLC – San Jose, CA

4.5 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

SS. PharmaLogic Austin, LLC – Austin, TX
TT. Sofie Co – Gilroy, CA

4.6 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-Appearance – **(FOR POSSIBLE ACTION)**

UU. ASAP Pharmacy – Orland Park, IL
VV. Cascade Specialty Pharmacy – Poulsbo, WA
WW. Costco Pharmacy #1710 – Madison, WI
XX. Cottrill's Pharmacy, Inc – Orchard Park, NY
YY. Fertility Pharmacy of America, LP – Nashville, TN
ZZ. Pantherx Specialty Pharmac – Collierville, TN
AAA. RARX II, LLC – Nashville, TN

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BBB. Roman Health Pharmacy – Buffalo Grove, IL
CCC. Strive Pharmacy Missouri, LLC –Fenton, MO
DDD. Triad Rx, Inc – Daphne, AL
EEE. TrustedmedRx, LLC – Boca Raton, FL
FFF. UrgentMedRx, LLC – Boca Raton, FL

4.7 Application for Out-of-State Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

4.8 Request to Engage in The Practice of Pharmacy at A Site Other Than a Licensed Pharmacy – Non-Appearance **(FOR POSSIBLE ACTION)**

GGG. Stephanie Andersson
HHH. Kara Balduzzi

4.9 Application for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Non-Appearance (**FOR POSSIBLE ACTION)**

III. Prosthetic Center of Excellence – Las Vegas, NV

Krystal Freitas recused herself from Item 4MM due to her employment.

President Park stated that Item 4RR had a correction to its business name and would be approved as “Wedgewood Connect LLC”.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, stated that Item 4P had confusion with the application but wanted to go forward. We will see another business application from them in the future.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Consent Agenda with the exception of Item 4MM.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: President Park moved to approve Item 4MM of the Consent Agenda.

Second: Adam Porath

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

G. DeeFlat Pharmacy	(24-282-PH-O)
H. Thu Thi Phuong Vo	(24-282-RPH-O)
I. Laughlin Pharmacy & Wellness Center	(24-289-PH-S)
J. Youjin Seo	(24-289-RPH-A-S)
K. Thu Thi Phuong Vo	(24-289-RPH-B-S)

Krystal Freitas disclosed that she knew Vo from school but could participate fairly in this matter and without bias.

Michael M. Lin appeared as counsel for Laughlin Pharmacy & Wellness Center and Youjin Seo.

Youjin Seo and Thu Thi Phuong Vo appeared and were sworn in by President Park prior to answering questions and offering testimony.

Courtney Sullivan appeared as counsel on behalf of Thu Thi Phuong Vo.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case alleging that the Respondents Laughlin Pharmacy, Seo and Vo dispensed adulterated and/or misbranded sterile drug products illegally compounded by DeeFlat Pharmacy using non-sterile methods.

Mr. Kandt noted that there is a pending change of ownership application for Laughlin Pharmacy & Wellness Center, in which Ms. Seo would have sole ownership of the pharmacy.

Mr. Kandt presented proposed stipulations for the Board's consideration.

The proposed stipulated penalties for DeeFlat Pharmacy, Pharmacy License No. PH04171, are the following:

Respondent DeeFlat Pharmacy's Pharmacy License No. PH04171 is revoked; 2) Respondent may not petition for reinstatement for a period of ten (10) years; 3) Respondent fined $20,000; and 4) Respondent assessed $2,000 in attorney's fees and costs,.

Ms. Sullivan represented that DeeFlat Pharmacy closed and has not been operational since June 2024, with no plans to reopen.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for DeeFlat Pharmacy as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

The Board discussed the proposed stipulated penalties for Vo, Laughlin Pharmacy & Wellness Center, and Seo and recommended revised penalties.

The amended stipulated penalties for Thu Thi Phuong Vo, Certificate of Registration No. 18661, are the following:

Respondent Vo's Certificate of Registration No. 18661 is revoked. The revocation is stayed, and Respondent placed on probation for a period of five (5) years subject to the following conditions:; 1) Respondent fined $5,000; 2) Respondent assessed $2,000 in attorney's fees and costs; 3) Respondent prohibited from acting as a managing pharmacist for any pharmacy licensed by the Board while on probation; 4) Respondent shall not hold an ownership interest with any pharmacy licensed by the Board while on probation; 4) Respondent shall not engage in compounding without completing certain enumerated training on compounding sterile and nonsterile drug products; and 5) Respondent shall comply with all laws while on probation.

Ms. Sullivan represented that her client, Ms. Vo, agreed to the amended stipulated penalties.

Board Action:

Motion: President Park moved to approve the Stipulation and Order for Thu Thin Phuong Vo as presented by Mr. Kandt, as amended.

Second: Jade Jacobo

Action: Passed unanimously.

The amended stipulated penalties for Youjin Seo, Certificate of Registration No. 18704, are the following:

Respondent Seo's Certificate of Registration No. 18704 is revoked. The revocation is stayed, and Respondent is placed on probation for a period of five (5) years subject to the following conditions: 1) Respondent fined $5,000; 2) Respondent assessed $2,000 in attorney's fees and costs; 3) Beginning sixty (60) days from the effective date of the

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order, Respondent prohibited from acting as a managing pharmacist for any pharmacy licensed by the Board while on probation; 4) Respondent shall not engage in compounding without completing certain enumerated training on compounding sterile and nonsterile drug products; and 5) Respondent shall comply with all laws while on probation.

There were no amendments to the proposed stipulated penalties for Laughlin Pharmacy & Wellness Center.

The proposed stipulated penalties for Laughlin Pharmacy & Wellness Center, Pharmacy License No. PH04520, are the following:

Respondent Laughlin Pharmacy & Wellness Center's Pharmacy License No. PH04520 is revoked. The revocation is stayed, and Respondent placed on probation for a period of three (3) years subject to the following conditions: 1) Respondent fined $12,000; 2) Respondent assessed $2,000 in attorney's fees and costs; 3) Respondent shall not engage in compounding without personnel completing certain enumerated training on compounding sterile and nonsterile drug products and undergoing certain inspections; and 4) Respondent shall comply with all laws while on probation.

Mr. Lin represented that his client, Ms. Seo, agreed to the amended stipulated penalties.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Youjin Seo and Laughlin Pharmacy as presented by Mr. Kandt, as amended.

Second: Krystal Freitas

Action: Passed unanimously.

7. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

   B. Laughlin Pharmacy – Laughlin, NV

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, gave a brief overview of the ownership and name change application for Laughlin Pharmacy, and questioned Ms. Seo on the business model and the daily activities of the pharmacy.

Board Action:

Motion: Jade Jacobo moved to approve the change of ownership and name change for Laughlin Pharmacy.

Second: Adam Porath

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Action: Passed unanimously.

F. Matthew Dikin (23-482-CS-S)

President Park recused herself from this matter due to her employment.

Adam Porath resided as the Presiding Officer.

Lyn Beggs appeared as counsel on behalf of Matthew Dikin.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Dikin issued a controlled substance prescription after the suspension of his Certificate of Registration No. CS26423. Respondent Dikin issued thirty-seven controlled substance prescriptions in Nevada while utilizing his DEA registration for Tennessee, failed to disclose criminal charges on his biennial renewal application, and failed to disclose the suspension of his license to practice osteopathic medicine.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 23-482-CS-S for the Board's consideration.

The proposed stipulated penalties for Matthew Dikin, Certificate of Registration No. CS26423, are the following:

Respondent Dikin's Certificate of Registration No. CS26423 is revoked. The revocation is stayed, and Respondent is placed on probation for a period of three (3) years with the following conditions: 1) public reprimand; 2) Respondent fined $7,000; and 3) Respondent assessed $3,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Matthew Dikin as presented by Mr. Kandt.

Second: Chanyis Taylor

Action: Passed unanimously.

L. Wilson Bernales (23-015-CS-S)

President Park disclosed that Wilson Bernales did work at her place of employment in the past, but she could participate in this matter fairly and without bias.

John Hunt appeared as counsel for Wilson Bernales.

Mr. Hunt stated that they do not oppose President Park presiding over the case.

Wilson Bernales appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Dr. Bernales made misleading statements or material omissions in applications for licensure in other jurisdictions.

Mr. Zunino presented a proposed Stipulation and Order for Case No. 23-015-CS-S for the Board's consideration.

The proposed stipulated penalties for Wilson Bernales, Certificate of Registration No. CS27754 are the following: 1) the Stipulation and Order will be a public reprimand; and 2) Dr. Bernales ordered to pay $750 to partially reimburse the Board for recoverable attorney fees and costs investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Wilson Bernales as presented by Mr. Zunino.

Second: Adam Porath

Action: Passed unanimously.

L. Safe Chain Solutions (24-356-WH-O)

William Stilling appeared as counsel on behalf of Safe Chain Solutions.

The parties stipulated to a continuance.

President Park continued the matter.

N. Jon Siems (24-390-CS-S)

No representative was present on behalf of Jon Siems, MD.

This matter has been continued to a future Board meeting.

P. Jack Thomas Jr. (22-187-CS-S)

No representative was present on behalf of Jack Thomas Jr.

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Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, prosecuted the case against Dr. Thomas Jr. alleging that he engaged in unprofessional and deceitful conduct. Mr. Zunino shared that Dr. Thomas Jr. stated in his Answer that he would not be present for the Board meeting, and believed he was not liable for the charges due to a contract where he sold his veterinary practice to another entity, however he continued to practice at the same facility.

Mr. Zunino requested the Board to continue with a default hearing.

Mr. Zunino requested the Board to make Findings of Fact consistent with paragraphs 3-24 of the amended Accusation, to make Conclusions of Law consistent with paragraphs 25-46 of the amended Accusation, and to make Findings of Guilt consistent with paragraphs 37-52 of the amended Accusation.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt Findings of Fact consistent with paragraphs 3-24 of the First Amended Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to adopt Conclusions of Law consistent with paragraphs 25-46 of the First Amended Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Dr. Thomas Jr. guilty of Counts 1-3, consistent with paragraphs 37-52 of the First Amended Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Zunino recommended the proposed discipline against Jack Thomas Jr.'s Certificate of Registration Nos. CS08932 and DV00496, as the following: 1) Certificate of

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Registration Nos. CS08932 and DV00496 to be placed in a Forfeited status; 2) Respondent receive a public reprimand; 3) Respondent to pay a $5,000 fine; and 4) Respondent to pay $2,128.50 to partially reimburse the Board for recoverable attorney fees and costs incurred in investigating and prosecuting this matter as they were reasonable, necessary, and actually incurred.

Board Action:

Motion: Jade Jacobo moved to declare as a matter of law that Dr. Thomas Jr.'s Certificate of Registration Nos. CS08932 and DV00496 were forfeited.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to file a public reprimand against Dr. Thomas Jr.'s Certificate of Registration Nos. CS08932 and DV00496.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve a fine of $5,000 against Dr. Thomas Jr.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award the attorney fees and costs of $2,128.50 on the basis that they were reasonable, necessary, and actually incurred.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

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Motion: Jade Jacobo moved to make the fine and attorney fees and costs due within 90 days from the effective date of the Order.

Second: Chanyis Taylor

Action: Passed unanimously.

7. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

A. Complete Care Pharmacy – Las Vegas, NV

Tristan Schukraft (new owner of Complete Care Pharmacy), Kema Ogden (former owner of Complete Care Pharmacy), and Eric Alonzo (Pharmacist in Charge) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave a brief overview of the application and questioned their business and business model.

Mr. Schukraft, Ms. Ogden, and Mr. Alonzo answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the ownership change for Complete Care Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

8. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. Owl Specialty Pharmacy – Covina, CA

Waleed Messiah, Senior Vice President of Specialty Operations, appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief overview of the application and questioned Mr. Messiah about the disclosure on their application and if Mr. Messiah outsources any pharmaceutical technicians from out-of-state that are not licensed.

President Park asked Mr. Messiah to send a letter to the Board to confirm that he was an authorized representative for Owl Specialty Pharmacy.

Mr. Messiah answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the new pharmacy application for Owl Specialty Pharmacy, pending a letter that supports he was an authorized representative and for updated information on the pharmacist in charge.

Second: Chanyis Taylor

Action: Passed unanimously.

10. Application for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLE ACTION)**

    B. Corstasis USA LLC – Henderson, NV – Background Check Not Required

Benjamin Esque, Chief Executive Officer appeared and was sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, questioned the applicant about their location and their business model.

Mr. Esque answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the wholesaler application for Corstasis USA LLC.

Second: Anna Carr

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

A. Jonathan Joel Runion

Jonathan Joel Runion appeared and was sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave an overview of the application to the Board and questioned Mr. Runion on his disclosure, what his treatment program entailed, and what other safeguards he had in place to ensure his access to controlled substances would be handled responsibly.

Mr. Runion answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve controlled substance registration for Jonathan Joel Runion.

Second: Adam Porath

Action: Passed unanimously.

R. Marcy Hanson (24-193-RPH-S)

No representative was present on behalf of Marcy Hanson.

Gregory Zunino, Senior General Counsel for Nevada State Board of Pharmacy, prosecuted the case alleging that Ms. Hanson failed to submit the required thirty (30) continuing education requirements to the Board for her biannual renewal period from November 1, 2021, through October 31, 2023.

Mr. Zunino would like to continue with a default hearing.

Mr. Zunino called Erin Miller as a witness.

Erin Miller, Administrative Assistant – Board Coordinator II, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Zunino questioned Ms. Miller on her position at the Nevada Board of Pharmacy and what her responsibilities were during the continuing education (CE) audit and the serving of the Notice of Hearing to Ms. Hanson.

Mr. Zunino requested the Board to find that the Notice of Hearing was properly served upon Ms. Hanson, to make Findings of Fact consistent with paragraphs 3-10 of the

Accusation, to make Conclusions of Law consistent with paragraphs 11-16 of the Accusation, and to find Ms. Hanson guilty of Count 1, consistent with paragraphs 17-19 of the Accusation.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that the Notice of Hearing was properly served upon Ms. Hanson, to adopt Findings of Fact consistent with paragraphs 3-10 of the Accusation, to make Conclusions of Law consistent with paragraphs 11-16 of the Accusation, and to find Ms. Hanson guilty of Count 1, consistent with paragraphs 17-19 of the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Zunino recommended the proposed discipline against Marcy Hanson's Certificate of Registration No. 09550, as the following: 1) Certificate of Registration No. 09550 will be revoked and 2) pay $500 to partially reimburse the Board for recoverable attorney fees and costs incurred while investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to revoke Marcy Hanson's Certificate of Registration No. 09550, effective immediately, and to award the attorney fees and costs in the amount of $500, due and payable within 90 days, on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

6. Appeal hearing pursuant to NRS 639.2895(2) **(FOR POSSIBLE ACTION)**

B. Heath DeHart

Heath DeHart appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, gave a brief overview of the procedural history of Mr. DeHart's case to the Board.

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Mr. DeHart provided testimony and documentary evidence in support of his request that the Board vacate its previous decision to uphold a $5,000 fine imposed by way of a citation issued pursuant to NRS 639.2895.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to vacate the $5,000 citation and fine for Heath DeHart.

Second: Chanyis Taylor

Aye: Porath, Taylor, Tomasso, Carr
Nay: Park, Jacobo

Action: Motion passed.

6. Appeal hearing pursuant to NRS 639.2895(2) **(FOR POSSIBLE ACTION)**

C. Nova Specialty Pharmacy

This matter was continued.

6. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Samuel Yu (22-185-CS-A-S)

This matter was continued.

B. Mee Han (22-185-CS-B-S)

This matter was continued.

C. Yuko Sweatt (22-214-CS-S)

This matter was continued.

D. Partell Pharmacy (23-239-PH-S)

This matter was continued.

E. Jeffrey Lang (23-239-RPH-S)

This matter was continued.

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M. John Katzen (24-389-CS-S)

This matter was continued.

O. Matthew Okeke (19-013-CS-S)

This matter was continued.

S. Xu Zhang (24-196-RPH-S)

This matter was continued.

T. Orthopedic Motion, Inc (24-281-MP-S)

This matter was continued.

U. John Devilbiss (24-243-RPH-S)

This matter was continued.

Public comment December 4, 2024, at 3:43PM

There was no public comment.

President Park recessed the meeting for the night and reconvened the meeting the next morning at 9:00 AM.

Board Members Present:

Helen Park	Krystal Freitas	Richard Tomasso	Adam Porath
Jade Jacobo	Chanyis Taylor	Anna Carr	

Board Staff Present:

David Wuest	Gregory Zunino	Brett Kandt	Monica Moazez
Darlene Nases	Erin Miller	Dena McClish	Jessette Phaynarikone
Joe Dodge	Darla Zarley	John Castaldo	Ken Scheuber
Leo Basch	Daniel Leon	Yenh Long	

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

David Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Open Meeting Laws for Nevada.

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Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present, and a quorum was established.

Public Comment December 5, 2024, 9:05 AM

There was no public comment.

◈ WORKSHOP ◈

Thursday, December 5, 2024 – 9:00 am

14. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION)**:

    A. **Amendment to the Nevada Administrative Code ("NAC") 639.** The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, presented the background on the proposed regulation.

President Park opened the floor for public comment.

There was no public comment.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, read the Nevada statute into the record.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the amendments to NAC 639 as presented by Ms. Long.

Second: Jade Jacobo

Action: Passed unanimously.

    B. **Amendment to the Nevada Administrative Code ("NAC") 639.742.** The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and

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provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, presented the background on the proposed regulation.

President Park opened the floor for public comment.

Rupesh Parikh from Comprehensive Cancer Center appeared and commented that he appeared previously requesting assistance in patient access for oncology drugs. He is in favor of the proposed regulation as it would help patients who live in more rural areas and face extended travel time to retrieve their medications.

Liz MacMenamin from the Retail Association of Nevada appeared and commented that they are in support of providing better patient access; however, her main concern is that this regulation isn't limited to oncologists only. This regulation may include dispensing practitioners that do not act in an ethical matter and will be able to dispense to patients without seeing or having a bona fide relationship. She requested that the Board take more time to review this regulation.

President Park closed the floor for public comment.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, commented that the authority cited on page 1 of the draft is incorrect, the authority cited should be NRS 639.070 and NRS 639.0727, instead of NRS 639.2177 and NRS 639.2327.

Board discussion ensued.

This matter was continued to a future Board meeting.

C. A REGULATION relating to controlled substances adding ethylphenidate and 2- methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

Darla Zarley, PMP Administrator for the Nevada Board of Pharmacy, presented the background on proposed regulation.

President Park opened the floor for public comment.

There was no public comment.

Board discussion ensued.

<u>Board Action:</u>

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Motion: Jade Jacobo moved to approve the proposed regulation amendment as presented by Ms. Zarley.

Second: Krystal Freitas

Action: Passed unanimously.

13. Election of Treasurer pursuant to NRS 639.040 - **(FOR POSSIBLE ACTION)**

The Board members voted to elect a new Board Treasurer.

Krystal Freitas nominated Adam Porath for Board Treasurer.

Adam Porath accepted the nomination.

Board discussion ensued.

Jade Jacobo – Yes
Anna Carr - Yes
Chanyis Taylor – Yes
Richard Tomasso – Yes
Helen Park – Yes
Krystal Freitas – Yes

Adam Porath was nominated as Board Treasurer.

8. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

   B. Truepill, LLC – Hayward, CA
   C. Truepill NY, LLC – Brooklyn, NY
   D. Seven Hills Pharmacy, LLC – Sharonville, OH

Marc Wagner appeared as counsel for Truepill.

Quynh Do (Senior Director of Pharmacy Practice and Compliance for Truepill), Michelle Meyer (Pharmacist in Charge – Truepill), Christopher Gibson (Assistant Pharmacist in Charge at Seven Hills Pharmacy), Christopher Lau (Pharmacist in Charge for Truepill - Hayward CA) appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background of the applications and ownership change. Mr. Wuest questioned the change in ownership and whether there will be any operational changes.

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The representatives answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the ownership change for Truepill, LLC – Hayward CA, Truepill NY, LLC – Brooklyn NY, and Seven Hills Pharmacy, LLC.

Second: Chanyis Taylor

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

D. Shouping Li

Shouping Li appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave an overview of the past discipline against Dr. Li by the Nevada Board of Pharmacy.

Mr. Li requested the Board remove the limitations on his controlled substance license, Certificate of Registration No. CS35340.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, read into record the minutes regarding the conditions placed on his Certificate of Registration No. CS35340.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to amend the conditions on Mr. Li's controlled substance registration, Certificate of Registration No. CS35340, with a 30 day maximum supply with no refills.

Second: Jade Jacobo

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

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E. Victor Jimenez Bonuel

Victor Jimenez Bonuel appeared and was sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave an overview of the application and questioned Dr. Bonuel to confirm whether he had other discipline cases against him in other states that were not disclosed on his controlled substance application.

Mr. Bonuel answered.

Board discussion ensued.

President Park asked if Dr. Bonuel would like to table his application to compile the necessary discipline documentation.

Mr. Bonuel agreed.

This application was tabled.

10. Application for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLE ACTION)**

B. Stericycle, Inc – McCarran, NV – Background Check Not Required

Joel Barr, Representative for Stericycle, Inc, appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, questioned Mr. Barr and asked him to give an overview of their business model and the intent for licensure.

Mr. Barr disclosed that they were just acquired by another company since the application was submitted.

Mr. Wuest commented that due to the company being acquired by a different entity, the Board will need the updated information submitted in order for Board staff to proceed with the application.

Board discussion ensued.

President Park asked Mr. Barr if he would like to table the application to provide the updated information to Board staff.

Mr. Barr agreed.

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This application was tabled.

9. Application for Out-of-State Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLE ACTION)**

    A. Covetrus North America, LLC – Canal Winchester, OH – Background Check Not Required

Kelly Ann Barnes (Senior Director for Regulatory Compliance), Phillip Mario Lombardi (Vice President of Operations and Logistics Services), and Jeffrey Hitchcock (Designated Representative) appeared and were sworn in by President Par prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave a brief overview of the application and questioned the products they plan to use, the training protocols for staff who handle drugs, and the disclosure listed on the application and changes made to rectify the issue.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the wholesaler and MDEG Admin application for Covetrus North America, LLC

Second: Chanyis Taylor

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    B. John Vennochi

John Vennochi appeared and was sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, asked Dr. Vennochi to confirm whether he wanted to remove Schedule I controlled substances on his application.

Dr. Vennochi confirmed that he would like Schedule I to be removed.

Ms. Moazez questioned Dr. Vennochi about the disclosure listed on his application and what steps he took in order to comply with the order.

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Richard Tomasso was excused from the meeting at 11:28AM.

Board discussion ensued.

Jade Jacobo was excused from the meeting at 11:36AM.

Adam Porath asked if Dr. Vennochi would like to table the application so Board staff can get a clearer understanding of his disclosures.

Dr. Vennochi agreed.

This application was tabled.

16. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative update

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented the Executive Secretary Report to the Board's satisfaction.

15. General Counsel Report

Gregory Zunino, Senior General Counsel, gave the General Counsel Report to the Board's satisfaction.

Jade Jacobo returned to the meeting at 1:00PM.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

F. William Clark

Lyn Beggs appeared as counsel on behalf of William Clark.

Willian Clark appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, gave an overview of the application and questioned Dr. Clark on his work experience over the past few years, where he is licensed, if he had discipline in any other states, and the

nature of the discipline against him.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the controlled substance registration for William Clark pending a favorable evaluation by PRN-PRN or equivalent.

Second: Krystal Freitas

Action: Passed unanimously.

C. Sherman Washington

This matter was continued.

12. Approval of Pharmacy Technician in Training Application - Appearance **(FOR POSSIBLE ACTION)**

A. Nicholas Dipirro

This matter was continued.

B. Thomas Lynch

This matter was tabled.

17. Public Comment

President Park opened the floor for public comment.

There was no public comment.

18. Date and Location of Next Scheduled Board Meeting:

January 15-16, 2025 – Las Vegas, NV

19. Adjournment

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4A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	■ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: 365 DME, LLC

MDEG Physical Address: 9860 Hudson Rd

City: Pittsford State: MI Zip: 49271-9861

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 517-997-5938 Website: https://www.365dme.com/

Email: Credentialing@365mbs.com

Name of MDEG Administrator (NAC 639.694): _____

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
■ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: CPAP Tubing
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:00-4:30	■ Tue: 8:00-4:30	■ Wed: 8:00-4:30	■ Thurs: 8:00-4:30	■ Fri: 8:00-4:30
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare:8004370001
Medicaid NJ:0978060 Medicaid MI:1780357764 Medicaid KY:7100960280 Medicaid SC:DM1713
Medicaid OH:004048799 Medicaid NC:1780357764 Medicaid IN:300091252

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Robyn Michelle Jones

Business Name: 365 DME

Business Address: 9860 Hudson Rd

City: Pittsford State: MI Zip: 49271-9861

Telephone: 517-997-5938 Email: Credentialing@365mbs.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones

Print Name of Authorized Person Submitting Application

Robyn M Jones

Original signature of Authorized Person (copies or stamps not accepted)

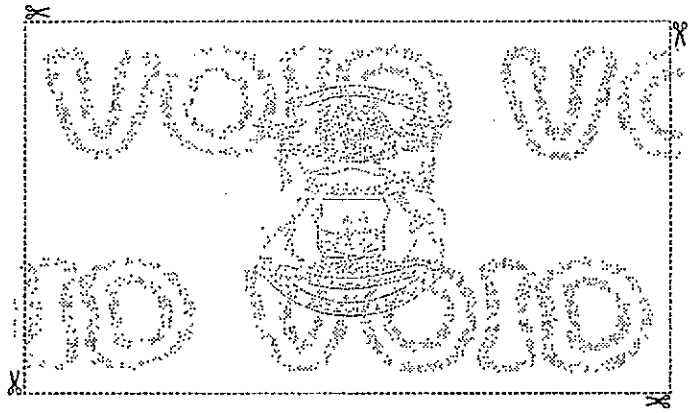
4/22/2024

Date

Board Use Only	Date Received: 9/24/24	Amount: $500-ck 31650

22TMP-0009PK

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909



365 DME LLC
DBA - 365 DME
9860 HUDSON RD
PITTSFORD, MI 49271

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

0782001

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY

WHOLESALE DISTRIBUTOR LICENSE

365 DME LLC
DBA - 365 DME
9860 HUDSON RD
PITTSFORD, MI 49271

LICENSE NO.	EXPIRATION DATE	
5306006880	12/17/2025	23298041001

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

0044

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

365 DME LLC

was validly authorized on March 19 , 2021, as a Michigan
DOMESTIC LIMITED LIABILITY COMPANY
and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 26th day of April , 2024.

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 24040599102

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

Filed by Corporations Division Administrator Filing Number: 221468979800 Date: 11/02/2021

MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

FILING ENDORSEMENT

This is to Certify that the CERTIFICATE OF ASSUMED NAME

for

365 DME LLC

ID Number: [redacted]

to transact business under the assumed name of
365 DME

received by electronic transmission on November 02, 2021 ***, is hereby endorsed.***

Filed on November 02, 2021***, by the Administrator.***

The document is effective on the date filed, unless a subsequent effective date within 90 days after received date is stated in the document.

Expiration Date: December 31, 2026

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau
TUEBOR
CIRCUMSPICE

In testimony whereof, I have hereunto set my hand and affixed the Seal of the Department, in the City of Lansing, this 2nd day of November, 2021.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

365DMEL-01 NCARLSON

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 8/7/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Nancy Carlson
Acrisure Great Lakes Partners Insurance Services, LLC 223 West Grand River Ave #1 Howell, MI 48843	PHONE (A/C, No, Ext): (231) 932-0265 FAX (A/C, No): E-MAIL ADDRESS: ncarlson@acrisure.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A : Benchmark Insurance Company — 41394
INSURED 365 DME, LLC 9860 Hudson Rd Pittsford, MI 49271	INSURER B :
	INSURER C :
	INSURER D :
	INSURER E :
	INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	☐ CLAIMS-MADE ☒ OCCUR			D1023G65884	8/11/2024	8/11/2025	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liab						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

INSURANCE VERIFICATION PURPOSES

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG 365 DME, LLC MDEG License # (if applicable) _____

Physical Address 9860 Hudson Rd

City Pills Feed State MI Zip 49271

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 517-997-5935 Website www.365DME.com

Licensing Company Email _____

Section 2: Personal Information

First Robyn Middle Michelle Last Jones

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Rd

City Osseo State MI Zip 49266

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwood High School		1992 - 1996	
Address	**City**	**State**	**Zip**
666 Lemoyne Road	Northwood	OH	43619
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Current	[redacted] Rd	Oregon	MI	43616
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - 2020	[redacted] Rd	Oregon	MI	43616
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
365 Medical Billing Services			2013 - Current
Business Address	**City**	**State**	**Zip**
115 S. Church St.	Hudson	MI	49247
Phone	**Title**	**Number of Employed Hours**	
517-368-6189	Owner	1,500 +	
Description of Duties			
Run the Company			

Business Name			From - To (MM/YY – MM/YY)
365 DME			2019 - Current
Business Address	**City**	**State**	**Zip**
4860 Hudson Rd	Pittsford	MI	49271
Phone	**Title**	**Number of Employed Hours**	
517-997-5938	Owner	1,500 +	
Description of Duties			
Run the Company			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

I, Robyn Jones, **certify that as the MDEG Administrator for**

365 DME, LLC,

that I (initial that you have read and meet the following requirements):

1. RJ Have a high school diploma or its equivalent;
2. RJ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RJ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RJ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones
Print Name (First, Last)

Robyn M Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Board Use Only	Date Received: 9/24/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site 365 DME, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) MI Wholesalers License:5306006880

Physical Address 9860 Hudson Rd

City Pittsford State MI Zip 49271

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 517-997-5938 Website www.365dme.com

Licensing Company Email Credentialing@365mbs.com

Section 2: Personal Information

First Robyn Middle Michelle Last Jones

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Rd

City Osseo State MI Zip 49266

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwood High School		1992-1996	
Address	**City**	**State**	**Zip**
600 Lemoyne Road	Northwood	OH	43619
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-current	[redacted] Peterson Rd	Osseo	MI	49266
2012-2020	[redacted] Beecher Rd	Osseo	MI	49266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
365 Medical Billing Services			2013-2024 (current)
Business Address	**City**	**State**	**Zip**
115 S Church St	Hudson	MI	49247
Phone	**Title**		
517-306-6189	OWNER		
Description of Duties			
Run the company			

Business Name			From - To (MM/YY – MM/YY)
365 DME			2019-2024 (current)
Business Address	**City**	**State**	**Zip**
9860 Hudson Rd	Pittsford	MI	49271
Phone	**Title**		
517-997-5938	Owner		
Description of Duties			
Run the company			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones

Print Name (First, Last)

Robyn M Jones

Original Signature (electronic, copies or stamps not accepted)

4/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Lenawee

I, Robyn Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robyn M Jones

Original Signature

9/4/2024

Date

Subscribed and Sworn to before me this 4 day of September.

Notary Public Signature

JOLENE PICKFORD
Notary Public, State of Michigan
County of Hillsdale
My Commission Expires 10-05-2030
Acting in the County of Hillsdale

(Seal)

365 DME, LLC
9860 Hudson Rd
Pittsford, MI 49271

365 DME, LLC is 100% owned and operated by Robyn Jones.

Robyn Jones
[redacted] Rd
Osseo, MI 49266

DOB: [redacted]

Thank you,

Robyn Jones
[redacted]
Owner
365 DME, LLC

4B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Cabretta LLC

MDEG Physical Address: 904 N 1400 W

City: St George State: UT Zip: 84770

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 866-755-7437 Website: _____

Email: camdenw@livelymedical.com

Name of MDEG Administrator (NAC 639.694): Sarah Waggoner

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: UltraViolet / UV light
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
☒ Mon: 9am-4pm.	☒ Tue: 9am-4pm.	☒ Wed: 9am-4pm.	☒ Thurs: 9am-4pm.	☒ Fri: 9am-4pm.
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
MEDICARE PTAN - 8239830001

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NA

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner 100%

Owner's Name: Sarah Waggoner

Business Name: Cabretta LLC

Business Address: 904 N 1400 W

City: St George State: UT Zip: 84770

Telephone: 866-755-7437 Email: Sarahw@livelymedical.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sarah Waggoner

Print Name of Authorized Person Submitting Application

Sarah Wag

Original signature of Authorized Person (copies or stamps not accepted)

9/6/24

Date

Board Use Only	Date Received: _____	Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of MDEG Sarah Waggoner MDEG License # (if applicable) _____

Physical Address 145W 300N

City Ivins State UT Zip 84738

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 866-755-7437 Website _____

Licensing Company Email Sarahw@livelymedical.com

Section 2: Personal Information

First Sarah Middle Ruth Last Waggoner

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]1400 W

City St George State UT Zip 84770

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Mountain View High School			From - To (MM/YY – MM/YY): 09/02 - 05/05
Address: 665 W Center St	City: Orem	State: UT	Zip: 84058
Diploma/Degree obtained, if any: General Education			
School Name: Utah Valley University			From - To (MM/YY – MM/YY):
Address: 800 W University Pkwy	City: Orem	State: UT	Zip: 84058
Diploma/Degree obtained, if any: N/A			
School Name: Southern Virginia University			From - To (MM/YY – MM/YY):
Address: 1 University Hill Dr	City: Buena Vista	State: VA	Zip: 24416
Diploma/Degree obtained, if any: N/A			
School Name:			From - To (MM/YY – MM/YY):
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:			From - To (MM/YY – MM/YY):
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21-Current	[redacted]	Ivins	UT	84738
09/13-04/21	[redacted]	Ivins	UT	84738

Sarah Wagg 9/10/24

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Cabretta DBA Lively			11/2022 - current
Business Address	**City**	**State**	**Zip**
904 N 1400 W	St. George	UT	84739
Phone	**Title**		**Number of Employed Hours**
866-755-7437	CEO		4310
Description of Duties			
Supply inventory, Management, ordering, staffing and licensing/insurance.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Rachel Wagner 9/10/24

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below: NA

Original Signature (electronic, copies or stamps not accepted)

8/8/24
Date

I, Sarah Waggoner, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. SW Have a high school diploma or its equivalent;
2. _____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sarah Waggoner
Print Name (First, Last)

Sarah Wag
Original Signature (electronic, copies or stamps not accepted)

8/8/24
Date

Board Use Only	Date Received: _____

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

UTAH DEPARTMENT OF COMMERCE
Division of Corporations and Commercial Code

MARGARET W. BUSSE
Executive Director

ADAM WATSON
Division Director

November 11, 2024

CERTIFICATE OF EXISTENCE

Registration Number:	9149631-0160
Business Name:	CABRETTA LLC
Principal Office Address:	904 N 1400 W, SAINT GEORGE, UT 84770
Registered Date:	09/04/2014
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Current Status:	ACTIVE - CURRENT

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division unless the status above is delinquent; and, that Articles of Dissolution have not been filed.

Adam Watson

Adam Watson
Director
Division of Corporations and Commercial Code

Certificate Number: 202411111423911
Enter the certificate number at https://businessregistration.utah.gov/ to verify this certification.

SPENCER J. COX
Governor
DEIDRE M. HENDERSON
Lieutenant Governor

State of Utah
Department of Commerce
Division of Professional Licensing

MARGARET W. BUSSE
Executive Director

MARK B. STEINAGEL
Division Director

VERIFICATION OF UTAH LICENSURE

Created On: 11/08/2024

This verification is considered a primary source from the State of Utah.

Name of Licensee (as it appears in our records): Cabretta LLC

Classification of License Issued: Pharmacy - Class E Business

Specialties: Durable Medical Equipment Providers

License Number: 12859638-1714

Obtained By: Application

Current Status: Active

Original Date of Licensure: 05/26/2022

Expiration Date: 09/30/2025

Agency and Disciplinary Action: NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**

Docket and Citation Number(s):

E-Prescriber:

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. This verification form does not show a complete history or interruptions in licensure. If you have any questions please contact the division.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/01/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Next First Insurance Agency, Inc.
PO Box 60787
Palo Alto, CA 94306

CONTACT NAME:
PHONE (A/C, No, Ext): (855) 222-5919 **FAX (A/C, No):**
E-MAIL ADDRESS: support@nextinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : State National Insurance Company, Inc.	12831
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Cabretta, LLC dba Lively
904 N 1400 W
Saint George, UT 84770

COVERAGES **CERTIFICATE NUMBER:** 559556322 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:	X		NXTWPJR79L-01-GL	12/12/2023	12/12/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$1,000,000.00 $100,000.00 $10,000.00 $1,000,000.00 $1,000,000.00 $1,000,000.00 $
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE $	$ $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The Certificate Holder is Novitas Solutions-NPEAST. This Certificate Holder is an Additional Insured on the General Liability policy per the Additional Insured Automatic Status Endorsement. All Certificate Holder privileges apply only if required by written agreement between the Certificate Holder and the insured, and are subject to policy terms and conditions.

CERTIFICATE HOLDER
Novitas Solutions-NPEAST
PO Box 3704
Mechanicsburg, PA 17055

LIVE CERTIFICATE
Click or scan to view

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Cabaretta LLA Dba: Lively
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 11449 60106
Physical Address 904 N 1400 W
City St. George State UT Zip 84770
Mailing Address (if different from physical address)
City State Zip
Telephone 866-755-7431 Website
Licensing Company Email

Section 2: Personal Information

First Sarah Middle Ruth Swain Last Waggoner
Alias(es, nicknames, name changes, etc.) Bennett
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted] 1400 W
City St. George State UT Zip 84770
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mountain View High School		'01-'05	
Address	City	State	Zip
	Orem	UT	84058
Diploma/Degree obtained, if any			
General ED			

School Name		From - To (MM/YY – MM/YY)	
Utah Valley University		'06-'07	
Address	City	State	Zip
	Orem	UT	84058
Diploma/Degree obtained, if any			
General ED			

School Name		From - To (MM/YY – MM/YY)	
Southern Virginia University		'05	
Address	City	State	Zip
	Buena Vista	VA	24416
Diploma/Degree obtained, if any			
MUSIC/MATH/GEN ED			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/20-Current	[redacted]	Ivins	UT	84738
09/13-04/20	[redacted]	Ivins	UT	84738
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Cabretta			From - To (MM/YY – MM/YY): 10/22-current
Business Address: 904 N 1400 W	City: St George	State: UT	Zip: 84770
Phone: 866-755-7437	Title: owner		
Description of Duties:			

Business Name: Vibrant Healthcare			From - To (MM/YY – MM/YY): 04/18-current
Business Address: 906 N 1400 W	City: St George	State: UT	Zip: 84770
Phone:	Title: owner		
Description of Duties:			

Business Name: Vibrant LLC			From - To (MM/YY – MM/YY): 9/14-current
Business Address: 906 N 1400 W	City: St. George	State: UT	Zip: 84770
Phone:	Title: owner		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	X	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2023-2024	06/24	PA		VSA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
[redacted]	

Reason/Charge
TCPA Violation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Gerard Jackson / Vibrant Healthcare	Lawsuit

Name of Business/Industry/Entity
Vibrant Healthcare / Healthcare Marketing

Provide explanation below:

Mr. Jackson Accused Vibrant Healthcare of TCPA violations. As per his deposition, Mr. Jackson was at the time filing the same claim against, 12 companies. The claim was dismissed and settled in Mediation to avoid more legal fees. Vibrant Healthcare, nor any of my other companies, have ever been accused of such violations prior to or since.

Thank you,

Gerard Wagh

Gerard Wagh
Original Signature (electronic, copies or stamps not accepted)

11/8/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sarah Waggoner
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/8/24
Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Washington

I, Sarah Waggoner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/8/24
Date

Subscribed and Sworn to before me this 8th day of November

Notary Public Signature

SONA ISKANDARYAN
NOTARY PUBLIC
STATE OF UTAH
MY COMM. EXPIRES NOV. 01, 2025
721139

(Seal)

4C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	■ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Dr. Micro Labs, LLC

MDEG Physical Address: 2400 Augusta Drive, Suite 194

City: Houston State: TX Zip: 77057

Mailing Address (if different from physical address): 2400 Augusta Drive, Suite 194

City: Houston State: TX Zip: 77057

Telephone: 817-393-7202 Website: _____

Email: cgayden@thewoundpros.com

Name of MDEG Administrator (NAC 639.694): Christina Gayden

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Durable Medical Equipment
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:00a-5:00p	■ Tue: 9:00a-5:00p	■ Wed: 9:00a-5:00p	■ Thurs: 9:00a-5:00p	☐ Fri:
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Dr. Micro Labs, LLC

Mailing Address: 2400 Augusta Drive, Suite 194

City: Houston State: TX Zip: 77057

Telephone: 817-393-7202 Email: cgayden@thewoundpros.com

Contact Person Name: Christina Gayden

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vanzil Burke

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/13/2024

Date

Board Use Only	Date Received: 12/3/24	Amount: $500-cc

APPLICATION FOR ANNUAL WHOLESALE LICENSE FOR DURABLE MEDICAL EQUIPMENT/MEDICAL GAS DISTRIBUTORS AND/OR RETAILERS

Attachments

- List of Name(s) and Titles(s) of Each Person [Owner/partner/corporate officer/director, etc]

  Vanzil Burke
  Sole Member and Managing Member

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Dr. Micro Labs, LLC (file number 804194583), a Domestic Limited Liability Company (LLC), was filed in this office on August 17, 2021.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 16, 2024.

Jane Nelson
Secretary of State

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

DR. MICRO LABS, LLC
2400 AUGUSTA DR STE 194
HOUSTON TX 77057

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

DR MICRO LABS LLC

2400 AUGUSTA DR STE 194
HOUSTON, TX 77057

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE DISTRIBUTOR

License # 1003030
Expires: April 27, 2026

NON-TRANSFERABLE

Commissioner

514017

Award of Accreditation

For DMEPOS Products & Services
Awarded to

Dr. Micro Labs, LLC
Houston, TX
HQAA ID # 1J0933I6K

On this day of

August 11, 2023

For the dedicated commitment of demonstrating high standards of quality in business and patient care.

HQAA
HEALTHCARE QUALITY ASSOCIATION ON ACCREDITATION

Executive Director

HQAA ACCREDITED

This accreditation award is in effect for three years from the above date.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 9/25/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Acrisure Partners West Coast Insurance Services, LLC
1950 W Corporate Way #1
Anaheim CA 92801

License#: 6009644
DRMICRO-01

CONTACT NAME: Jessica DePriest
PHONE (A/C, No, Ext): 408-350-5700
FAX (A/C, No):
E-MAIL ADDRESS: WestCerts@acrisure.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Gemini Insurance Company	10833
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Dr. Micro Labs
2400 Augusta Dr STE 194
Houston TX 77057-4922

COVERAGES **CERTIFICATE NUMBER:** 428888586 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			VNPL016865	8/27/2024	8/27/2025	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 50,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Prof Liability - Claims Made			VNPL016865	8/27/2024	8/27/2025		3,000,000 3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

National Provider Enrollment
Palmetto GBA, AG-495
PO Box 100142
Columbia SC 29202

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Dr. Micro Labs, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2400 Augusta Drive, Suite 194

City: Houston State: TX Zip: 77057

Mailing Address (if different from physical address): 2400 Augusta Drive, Suite 194

City: Houston State: TX Zip: 77057

Telephone: 817-393-7202 Website:

Licensing Company Email: nawa@thewoundpros.com

Section 2: Personal Information

First: Vanzil Middle: Tilden Last: Burke

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Los Angeles State: CA Zip: 90017

Telephone: Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Florida A&M University			08/94-05/00
Address	**City**	**State**	**Zip**
1601 S. Martin Luther King Jr.	Tallahassee	FL	32307
Diploma/Degree obtained, if any			
Bachelor of Arts & Science			

School Name			From - To (MM/YY – MM/YY)
East Laurens High School			08/90-05/94
Address	**City**	**State**	**Zip**
1010 US - 80	East Dublin	GA	31027
Diploma/Degree obtained, if any			
Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19-Current	[redacted]	Los Angeles	CA	90017
11/16-11/19	[redacted]	Beverly Hills	CA	90211
11/14-11/16	[redacted]	Beverly Hills	CA	90212

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
The Burke Management Firm, LLC			01/07-Present
Business Address	**City**	**State**	**Zip**
231 S. Gale Drive	Beverly Hills	CA	90211
Phone	**Title**		
(310) 927-3946	Owner; CEO		
Description of Duties			
Oversees daily operations and activities of clients			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vanzil Burke

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/13/2044

Date

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 13 day of November, 2024, by Vanzil Burke

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

GEORGINA C. SAEZ
COMM # 2381256
Los Angeles County
California Notary Public
Comm Exp Nov. 2, 2025

(Seal)

Signature G. Saez

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles)

On 11/13/2024 before me, Georgina C. Saez, Notary Public
(insert name and title of the officer)

personally appeared Vanzil Burke,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

GEORGINA C. SAEZ
COMM # 2381256
Los Angeles County
California Notary Public
Comm Exp Nov. 2, 2025

Signature G. Saez (Seal)

Clear Form Print Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Dr. Micro Labs, LLC MDEG License # (if applicable) _____

Physical Address 2400 Augusta Drive, Suite 194

City Houston State TX Zip 77057

Mailing Address (if different from physical address) _____

City Houston State TX Zip 77057

Telephone 713-393-7202 Website under construction

Licensing Company Email cgayden@thewoundpros.com

Section 2: Personal Information

First Christina Middle Yvette Last Gayden

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Valley Club Dr

City Houston State Tx Zip 77078

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
East High School		08/1996-05/2000	
Address	**City**	**State**	**Zip**
3206 Poplar Ave	Memphis	Tn	38111
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		05/2020-07/2023	
Address	**City**	**State**	**Zip**
4035 S Riverpoint Pkwy	Phoenix	Az	85040
Diploma/Degree obtained, if any			
Degree			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/24-current	[redacted]	Houston	Tx	77078
06/23-10/24	[redacted]	Houston	Tx	77082
05/22-06/23	[redacted]	Memphis	Tn	38116
04/19-05/22	[redacted]	Memphis	Tn	38116
04/89-04/19	[redacted]	Bartlett	Tn	38135
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
The Wound Pros			03/2022-current	
Business Address		City	State	Zip
5901 West Century Blvd.		Los Angeles	CA	90045
Phone	Title		Number of Employed Hours	
713-393-7202	Associate State Office Administrator		4000	
Description of Duties				
I assist with creating medical records, billing, customer support, product knowledge, and any other duties needed to be performed for the company.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/18/2024
Date

I, Christina Y. Gayden, **certify that as the MDEG Administrator for**

Dr. Micro Labs, LLC,

that I (initial that you have read and meet the following requirements):

1. CG Have a high school diploma or its equivalent;
2. CG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

State of Texas
County of Harris

This instrument was acknowledged before me on 11 day of 10, 2024 by Christina Gayden

Notary Public's Signature
My Commission Expires May, 05, 2028

Christina Gayden
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/18/2024
Date

FRANK AUGUSTO VALDERRAMA
My Notary ID # 126468419
Expires May 5, 2028

Board Use Only	Date Received: 12/3/24

4D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Eastern Pulmonary Services, Inc. dba Eastern Medtech

MDEG Physical Address: 277 South St, Ste. 1

City: Walpole State: MA Zip: 02081

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (857) 400-0044 Website: http://www.easternmedtech.com

Email: support@easternmedtech.com

Name of MDEG Administrator (NAC 639.694): _____

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am-5pm ET	■ Tue: 9am-5pm ET	■ Wed: 9am-5pm ET	■ Thurs: 9am-5pm ET	■ Fri: 9am-5pm ET
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
1700884798 (Medicare NPI)
0231200001 (Medicare PTAN)

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Massachusetts

Parent Company (if any): N/A

Corporation/Organization Name: Eastern Pulmonary Services, Inc. dba Eastern Medtech

Mailing Address: 277 South St, Ste. 1

City: Walpole State: MA Zip: 02081

Telephone: (857) 400-0044 Email: admin@eastermedtech.com

Contact Person Name: Alexa Cohen, Operations Manager

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Felkay

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/5/2024

Date

Board Use Only	Date Received: 10/14/24	Amount: $500-cc

MA SOC Filing Number: 202483116780 Date: 7/23/2024 1:03:23 PM

The Commonwealth of Massachusetts, William Francis Galvin

Corporations Division

One Ashburton Place - Floor 17, Boston MA 02108-1512 | Phone: 617-727-9640

Annual Report

(General Laws, Chapter 156D, Section 16.22; 950 CMR 113.57)

Minimum Filing Fee: $100.00

Identification Number: 042922096

1. Exact name of the corporation:

EASTERN PULMONARY SERVICES, INC.

2,3. Street address of the corporation registered office in the commonwealth and the name of the registered agent at that office:

Agent name: GIL RABINOVSKY

Number and street: 277 SOUTH STREET, SUITE 1

Address 2: PINE BROOK OFFICE PARK

City or town: WALPOLE State: MA Zip code: 02081

4. Street address of the corporation's principal office:

Number and street: 277 SOUTH STREET

Address 2: SUITE 1

City or town: WALPOLE State: MA Zip code: 02062

Country: UNITED STATES

5. Provide the name and addresses of the corporation's board of directors and its president, treasurer, secretary, and if different, its chief executive officer and chief financial officer.

Title	Individual Name	Address
PRESIDENT	GIL RABINOVSKY	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
TREASURER	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
SECRETARY	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
CEO	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
DIRECTOR	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
DIRECTOR	GIL RABINOVSKY	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA

Name and Contact Information for Controlling Owners

Peter Falkson, [redacted], CEO, 75%, [redacted]
Newton MA 02461, [redacted]

Gil Rabinovsky, [redacted], President 25%,
[redacted] Sharon, MA 02067

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the Commonwealth

July 23, 2024

TO WHOM IT MAY CONCERN:

I hereby certify that according to records in this office,

EASTERN PULMONARY SERVICES, INC.

was incorporated under the General Laws of this Commonwealth on **June 10, 1986**.

I further certify that no amendments to the Articles of Organization appear of record here and said corporation still has legal existence.

I also certify that in an Annual Report filed here for fiscal year **2024**, the Officers and Directors are listed as follows:

SEE ATTACHED

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Processed By:BOD

MA SOC Filing Number: 202483116780 Date: 7/23/2024 1:03:23 PM

A TRUE COPY ATTEST
WILLIAM FRANCIS GALVIN
SECRETARY OF THE COMMONWEALTH
DATE 7/24/2024 CLERK HN

The Commonwealth of Massachusetts, William Francis Galvin

Corporations Division

One Ashburton Place - Floor 17, Boston MA 02108-1512 | Phone: 617-727-9640

Annual Report

(General Laws, Chapter 156D, Section 16.22; 950 CMR 113.57)

Minimum Filing Fee: $100.00

Identification Number: [redacted]

1. Exact name of the corporation:

EASTERN PULMONARY SERVICES, INC.

2,3. Street address of the corporation registered office in the commonwealth and the name of the registered agent at that office:

Agent name: GIL RABINOVSKY

Number and street: 277 SOUTH STREET, SUITE 1

Address 2: PINE BROOK OFFICE PARK

City or town: WALPOLE State: MA Zip code: 02081

4. Street address of the corporation's principal office:

Number and street: 277 SOUTH STREET

Address 2: SUITE 1

City or town: WALPOLE State: MA Zip code: 02062

Country: UNITED STATES

5. Provide the name and addresses of the corporation's board of directors and its president, treasurer, secretary, and if different, its chief executive officer and chief financial officer.

Title	Individual Name	Address
PRESIDENT	GIL RABINOVSKY	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
TREASURER	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
SECRETARY	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
CEO	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
DIRECTOR	PETER FALKSON	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA
DIRECTOR	GIL RABINOVSKY	277 SOUTH STREET, SUITE 1 WALPOLE, MA 02081 USA

6. Briefly describe the business of the corporation:

DISTRIBUTOR OF MEDICAL EQUIPMENT & SUPPLIES

7. Capital stock of each class and series:

Class of Stock	Par value per share (Enter 0 if no Par)	Total authorized number of shares	Total authorized par value	Total issued and outstanding number of shares
CNP	0	1,000	0	1,000

8. Check here if the stock of the corporation is publicly traded:

☐

9. Report is filed for fiscal year ending: 12/31/2024

Signed by GIL RABINOVSKY , its PRESIDENT

on this 23 Day of July, 2024

Award of Accreditation

For DMEPOS Products & Services
Awarded to

Eastern Pulmonary Services, Inc.
d/b/a: Eastern Sleep & Respiratory
Walpole, MA
HQAA ID # MRBWZO3EX
On this day of

June 6, 2023

For the dedicated commitment of demonstrating high standards of quality in business and patient care.

HQAA
HEALTHCARE QUALITY ASSOCIATION ON ACCREDITATION

Executive Director

HQAA ACCREDITED

This accreditation award is in effect for three years from the above date.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/15/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Kim Kulish PHONE (A/C, No, Ext): (319) 274-4492 FAX (A/C, No): E-MAIL ADDRESS: Kim.Kulish@vgm.com
INSURED: Eastern Pulmonary Services Inc Eastern MedTech 277 South St STE 1 Walpole MA 02081	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A : BENCHMARK INSURANCE COMPANY 41394 INSURER B : BENCHMARK INSURANCE COMPANY 41394 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X Professional Liability GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:			D1023 G7086-1	03/12/2024	03/12/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS HIRED AUTOS NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N [ ] N / A If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
B	Cyber Liability			D1023 G7086-1	03/12/2024	03/12/2025	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

Tel: 617-624-6000
www.mass.gov/dph

MAURA T. HEALEY
Governor
KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary
ROBERT GOLDSTEIN, MD, PhD
Commissioner

Verification of Licensure

08/01/2024

To Whom It May Concern:

The organization named below has received the following in the Commonwealth of Massachusetts:

Drug Manufacturer or Drug Distributor Controlled Substance Registration

Name of Organization: Eastern Pulmonary Services

Registration Number: RMD400015
Registration Status: Current
Issue Date: 05/22/2023
Expiration Date: 05/22/2025
Disciplinary Actions: There are no disciplinary actions against this registration.

Registration verification may be obtained at http://checkahealthlicense.mass.gov/. The information provided in this "Verification" is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the "Verification." Disciplinary status is defined as voluntary surrender, revocation, suspension or probation of a license. The "Verification" does not include information about the existence, absence, or status of complaints. To request such information, please submit a public record request to publicrecordsadmin@massmail.state.ma.us.

Traci Westgate

Traci Westgate
Director

01b4e0f2-a2a2-43f2-b1a5-c62e31037e30

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Eastern Pulmonary Services, Inc. dba Eastern Medtech

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): RMD400015 (Massachusetts)

Physical Address: 277 South St., Ste.1

City: Walpole State: MA Zip: 02081

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (857) 400-0044 Website: https://www.easternmedtech.com

Licensing Company Email: support@easternmedtech.com

Section 2: Personal Information

First: Gil Middle: Felix Last: Rabinovsky

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] St

City: Sharon State: MA Zip: 02067

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Ben Gurion University of the Negev			86 - 90	
Address		City	State	Zip
David Ben Gurion Blvd. 1, Beer Sheva 8410		Israel	Israel	
Diploma/Degree obtained, if any				
Electrical & computer Engineer				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/1/2007	[redacted]	Sharon	MA	02067
From - To (MM/YY – MM/YY)	Address	City	State	Zip
NA	NA	NA	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Eastern Pulmonary Services, Inc. DBA Eastern Medtech			From - To (MM/YY – MM/YY): 3/2018
Business Address: 277 South Street, Ste. 1	City: Walpole	State: MA	Zip: 02081
Phone: (857) 400-0044	Title: President		
Description of Duties: NA			

Business Name: NA			From - To (MM/YY – MM/YY): NA
Business Address: NA	City: NA	State: NA	Zip
Phone: NA	Title: NA		
Description of Duties: NA			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/4/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gil Rabinovsky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10.5.24

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Norfolk

I, Gil Felix Rabinovsky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10.8.24

Date

Subscribed and Sworn to before me this 8th day of October, 2024

Notary Public Signature Houda Ayoub

HOUDA F AYOUB
Notary Public
Massachusetts
My Commission Expires
Mar 6, 2031

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Eastern Pulmonary Services, Inc. d/b/a Eastern Medtech — MDEG License # (if applicable): N/A

Physical Address: 277 South St., Ste. 1

City: Walpole — State: MA — Zip: 02081

Mailing Address (if different from physical address): (Same)

City: N/A — State: N/A — Zip: N/A

Telephone: 857-400-0044 — Website: https://www.easternmedtech.com

Licensing Company Email: credentialing@visioneraus.org

Section 2: Personal Information

First: Peter — Middle: James — Last: Falkson

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Boylston St.

City: Newton Highlands — State: MA — Zip: 02461

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Westwood High School			From - To (MM/YY – MM/YY): 7/1982 – 6/1986	
Address: Manchester St	City: Westwood		State: MA	Zip: 02090
Diploma/Degree obtained, if any: High School Degree				
School Name: Boston University			From - To (MM/YY – MM/YY): 9/1986 – 5/1990	
Address: Comm Ave	City: Boston		State: MA	Zip: 02115
Diploma/Degree obtained, if any: BSBA				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
June 2022 – Current	[redacted]	Newton	MA	02461
9/2012 – June 2022	[redacted]	Chestnut Hill	MA	02467
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Custom Medtech			From - To (MM/YY – MM/YY): 9/2018 – Current
Business Address: 277 South St, #2	City: Holyoke	State: MA	Zip: 01040
Phone: 857-400-4444	Title: CEO		Number of Employed Hours: 33,280
Description of Duties: Run Company			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/6/2024
Date

I, Peter James Falkson, **certify that as the MDEG Administrator for**

Eastern Pulmonary Services, Inc. d/b/a Eastern Medtech,

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Falkson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/6/2024
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Eastern Pulmonary Services, Inc. dba Eastern Medtech

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): RMD400015 (Massachusetts)

Physical Address: 277 South St., Ste.1

City: Walpole State: MA Zip: 02081

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email: credentialing@visioneraus.org

Section 2: Personal Information

First: Peter Middle: James Last: Faulkson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] St.

City: Newton State: MA Zip: 02461

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		/
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		/
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		/

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Westwood High School			From - To (MM/YY – MM/YY): 9/1922 – 6/1926	
Address: Manchester St	City: Westwood		State: MA	Zip: 02090
Diploma/Degree obtained, if any: High School Degree				
School Name: Boston University			From - To (MM/YY – MM/YY): 9/1986 – 5/1990	
Address: Comm Ave	City: Boston		State: MA	Zip: 02115
Diploma/Degree obtained, if any: BSBA				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
June 2022 - Current	[redacted]	Newton	MA	02461
9/2012 - June 2022	[redacted]	Chestnut Hill	MA	02467
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Custom Medtech				From - To (MM/YY – MM/YY): 9/2018 – Current
Business Address: 277 South St, #2	City: Walpole		State: MA	Zip: 02021
Phone: 857-400-4444	Title: CEO		Number of Employed Hours: 33,280	
Description of Duties: Run Company				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ 10/8/2024

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Faulkson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/2/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Norfolk

I, Peter Faulkson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/2/2024

Date

Subscribed and Sworn to before me this 8th day of October, 2024

Houda Ayoub

Notary Public Signature

HOUDA F AYOUB
Notary Public
Massachusetts
My Commission Expires
Mar 6, 2031

(Seal)

4E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: A.R. Hinkel Co., Inc dba R.A. Fischer Company

MDEG Physical Address: 5400 Atlantis Court

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-525-3467 Website: www.rafischer.com

Email: jen@arhinkel.com

Name of MDEG Administrator (NAC 639.694): Jennifer Jacobellis - Application Pending

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Tap Water Iontophoresis Device, PureWick
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am - 4:30pm	■ Tue: 9am - 4:30pm	■ Wed: 9am - 4:30pm	■ Thurs: 9am - 4:30pm	■ Fri: 9am - 4:30pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(l))
Medicare Provider Number: PTAN-7934970001

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): _____

Corporation/Organization Name: A.R. Hinkel Co., Inc dba R.A. Fischer Company

Mailing Address: 5400 Atlantis Court

City: Moorpark State: CA Zip: 93021

Telephone: 800-525-3467 Email: jen@arhinkel.com

Contact Person Name: Jennifer Jacobellis

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓ ✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓ ✓	✓	✓
• **Medical products provider located** outside of this State **must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓ ✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓ ✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓ ✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓ ✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jennifer Jacobellis

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/22/2024

Date

Board Use Only	Date Received: 11/26/24	Amount: $500-CK 1638

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	A. R. HINKEL CO., INC.
Entity No.:	1381818
Registration Date:	07/30/1986
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 29, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 261051518

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

A.R Hinkel Co Inc
5400 Atlantis Court
Moorpark, , CA 93021

LICENSE NUMBER: 115701
EXPIRATION DATE: 2/9/2025

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 05/23/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Ryan Archer	
Archer Insurance Agency 650 Hampshire Rd Suite 100 Westlake Village CA 91361	PHONE (A/C, No, Ext): (805) 421-4000	FAX (A/C, No): (805) 421-4007
	E-MAIL ADDRESS: certificates@archeragent.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : HARTFORD UNDERWRITERS INS CO	30104
	INSURER B : EVANSTON INS CO	35378
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

INSURED
A R Hinkel dba: RA Fischer
5400 Atlantis Court
Moorpark CA 93021

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:	Y		81 SBA BD1Y9Z	02/18/2024	02/18/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 2,000,000 $ 1,000,000 $ 10,000 $ 2,000,000 $ 4,000,000 $ Excluded $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY	Y		81 SBA BD1Y9Z	02/18/2024	02/18/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 2,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ 10000	N		81 SBA BD1Y9Z	02/18/2024	02/18/2025	EACH OCCURRENCE AGGREGATE PR/COMP OPS AGG	$ 1,000,000 $ 1,000,000 $ Excluded
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
B	Products Liability			MKLV5PLS000315	02/26/2024	02/26/2025	Each Claim Aggregate	$1,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Board of Certification/Accreditation is additionally insured on the general liability policy listed above.

Location: 5400 Atlantis Court Suite A, Moorpark, CA 93021

CERTIFICATE HOLDER

Board of Certification/Accreditation
10461 Mill Run Circle, Suite 1250
Owning Mills MD 21117

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: A.R. Hinkel Co., Inc. MDEG License # (if applicable): app. pending

Physical Address: 5400 Atlantis Court

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 800-525-3467 Website: www.rafischer.com

Licensing Company Email: JEN@ ARHINKEL . COM

Section 2: Personal Information

First: Jennifer Middle: Ann Last: Jacobellis

Alias(es, nicknames, name changes, etc.): Jennifer Ann Honda (Maiden Name, changed 01/2012)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Santa Rosa Valley State: CA Zip: 93021

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State Uninriversity Northridge		01/01/ - 05/04	
Address	**City**	**State**	**Zip**
18111 Nordhoff Street	Northridge	CA	91324
Diploma/Degree obtained, if any			
Bachelor of Science - Accounting & Economics			

School Name		From - To (MM/YY – MM/YY)	
Pierce College		08/00 - 05/02	
Address	**City**	**State**	**Zip**
6201 Winnetka Avenue	Woodland Hills	CA	91371
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		8/99 - 05/00	
Address	**City**	**State**	**Zip**
1 LMU Drive	Los Angeles	CA	90045
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Chaminade College Preparatory High School		08/95 - 06/99	
Address	**City**	**State**	**Zip**
7500 Chaminade Avenue	Canoga Park	Ca	91304
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - Current	[redacted]	Santa rosa valley	CA	93012
02/11 - 09/20	[redacted]	Simi Valley	CA	93065

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
A.R. Hinkel Co., Inc.			02/19 - Current	
Business Address		**City**	**State**	**Zip**
5400 Atlantis Court		Moorpark	CA	93021
Phone	**Title**		**Number of Employed Hours**	
800-525-3467	Owner, President/CEO		15,000+	
Description of Duties				
Oversee daily operations, financials, business strategy, compliance, human resources				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/22/2024
Date

I, Jennifer Ann Jacobellis, **certify that as the MDEG Administrator for**

A.R. Hinkel Co., Inc. DBA R.A. Fischer Company,

that I (initial that you have read and meet the following requirements):

1. JJ Have a high school diploma or its equivalent;
2. JJ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JJ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JJ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JENNIFER JACOBELLIS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/2024

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: A.R. Hinkel Co., Inc DBA R.A. Fischer Company

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Application pending

Physical Address: 5400 Atlantis Court

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 800-525-3467 Website: www.rafischer.com

Licensing Company Email: _____

Section 2: Personal Information

First: Jennifer Middle: Ann Last: Jacobellis

Alias(es, nicknames, name changes, etc.): Jennifer Ann Honda (Maiden Name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Santa Rosa Valley State: CA Zip: 93012

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University Northridge		01/01 - 05/04	
Address: 18111 Nordhoff Street	City: Northridge	State: CA	Zip: 91324
Diploma/Degree obtained, if any: Bachlor of Science - Accounting & Economics			

School Name		From - To (MM/YY – MM/YY)	
Pierce College		08/00 - 05/02	
Address: 6201 Winnetka Avenue	City: Woodland Hills	State: CA	Zip: 91371
Diploma/Degree obtained, if any: Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		8/99 - 05/00	
Address: 1 LMU Drive	City: Los Angeles	State: CA	Zip: 90045
Diploma/Degree obtained, if any: none			

School Name		From - To (MM/YY – MM/YY)	
Chaminade College Preparatory High School		08/95 - 06/99	
Address: 7500 Chaminade Avenue	City: Canoga Park	State: CA	Zip: 91304
Diploma/Degree obtained, if any: High Schol Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Current	[redacted]	Santa Rosa Valley	CA	93012
2011-2020	[redacted]	Simi Valley	CA	93065

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
A.R. Hinkel Co., Inc. DBA R.A. Fischer Company			02/16 - Current
Business Address	**City**	**State**	**Zip**
5400 Atlantis Court	Moorpark	CA	93021
Phone	**Title**		
800-525-3467	Owner, President/CEO		
Description of Duties			
Oversee daily operations, financials, business strategy, compliance			

Business Name			From - To (MM/YY – MM/YY)
Fischer Medical Supply			11/21 - Current
Business Address	**City**	**State**	**Zip**
5400 Atlantis Court, Suite C	Moorpark	CA	93021
Phone	**Title**		
800-573-1399	Owner, President/CEO		
Description of Duties			
Oversee daily operations, financials, business strategy, marketing			

Business Name			From - To (MM/YY – MM/YY)
WIS Enterprises, Inc			04/20 - Current
Business Address	**City**	**State**	**Zip**
5400 Atlantis Court, Suite C	Moorpark	CA	93021
Phone	**Title**		
818-470-0824	Owner, President/CEO		
Description of Duties			
Oversee creative design, product development, e-commerce, sales and strategy			

Business Name			From - To (MM/YY – MM/YY)
FTP Enterprises			06/14 - 2/16
Business Address	**City**	**State**	**Zip**
2016 Freeeborn Way	Santa Rosa Valley	CA	93012
Phone	**Title**		
818-470-0824	Owner, Secretary		
Description of Duties			
accounting and bookkeeping			

Business Name			From - To (MM/YY – MM/YY)
AVL Staffing Inc			06/23 - Current
Business Address	**City**	**State**	**Zip**
2016 Freeborn Way	Santa Rosa Valley	CA	93012
Phone	**Title**		
877-516-0218	Owner, CEO		
Description of Duties			
Oversee business strategy, financials, human resources			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/22/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JENNIFER JAUSELY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Ventura

I, JENNIFER JAUSELY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/22/2024

Date

Subscribed and Sworn to before me this 22 day of November, 2024

Becky R Jensen

Notary Public Signature

BECKY R. JENSEN
Notary Public - California
Ventura County
Commission # 2450889
My Comm. Expires Jun 20, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: A.R. Hinkel Co., Inc DBA R.A. Fischer Company

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Application pending

Physical Address: 5400 Atlantis Court

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 800-525-3467 Website: www.rafischer.com

Licensing Company Email:

Section 2: Personal Information

First: Luca Middle: Andrew Last: Jacobellis

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Santa Rosa Valley State: CA Zip: 93012

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University Northridge		09/98 - 05/03	
Address	**City**	**State**	**Zip**
18111 Nordhoff Street	Northridge	CA	91324
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Pierce College		09/98 - 05/99	
Address	**City**	**State**	**Zip**
6201 Winnetka Avenue	Woodland Hills	CA	91371
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Chaminade College Preparatory High School		08/94 - 06/98	
Address	**City**	**State**	**Zip**
7500 Chaminade Avenue	Canoga Park	CA	91304
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Current	[redacted]	Santa Rosa Valley	CA	93012
2011-2020	[redacted]	Simi Valley	CA	93065

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
A.R. Hinkel Co., Inc.			02/16 - Current	
Business Address		**City**	**State**	**Zip**
5400 Atlantis Court		Moorpark	CA	93021
Phone	**Title**			
800-525-3467	Owner, Secretary			
Description of Duties				
No direct involvement				

Business Name			From - To (MM/YY – MM/YY)	
Fischer Medical Supply			11/21 - Current	
Business Address		**City**	**State**	**Zip**
5400 Atlantis Court, Suite C		Moorpark	CA	93021
Phone	**Title**			
800-573-1399	Owner, Officer			
Description of Duties				
No direct involvement				

Business Name			From - To (MM/YY – MM/YY)	
WIS Enterprises, Inc			04/20 - Current	
Business Address		**City**	**State**	**Zip**
5400 Atlantis Court, Suite C		Moorpark	CA	93021
Phone	**Title**			
818-470-0824	Owner, Secretary			
Description of Duties				
No direct involvement				

Business Name			From - To (MM/YY – MM/YY)	
FTP Enterprises			06/19 - Current	
Business Address		**City**	**State**	**Zip**
2016 Freeeborn Way		Santa Rosa Valley	CA	93012
Phone	**Title**			
818-470-0824	Owner, Secretary			
Description of Duties				
IT Consulting				

Business Name			From - To (MM/YY – MM/YY)	
1Path Managed Services, LLC			12/19 - Current	
Business Address		**City**	**State**	**Zip**
2300 Windy Ridge Pkwy, Suite 685 South		Atlanta	GA	30339
Phone	**Title**			
877-516-0218	Chief of Operations			
Description of Duties				
Oversee operations of outsourced managed IT services business				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
CalNet Enterprises			10/01 - 06/19
Business Address	**City**	**State**	**Zip**
9420 Topanga Canyon Blvd, Suite 100	Chatsworth	CA	91311
Phone	**Title**		
818-701-5753	President/COO		
Description of Duties			
Oversee sales and operations of outsourced managed IT services business			

Business Name			From - To (MM/YY – MM/YY)
5400 Atlantis LLC			08/2021 - Current
Business Address	**City**	**State**	**Zip**
2016 Freeborn Way	Santa Rosa Valley	CA	93012
Phone	**Title**		
818-554-4088	Owner		
Description of Duties			
Rental property management			

Business Name			From - To (MM/YY – MM/YY)
17710 Merridy LLC			06/2019 - Current
Business Address	**City**	**State**	**Zip**
2016 Freeborn Way	Santa Rosa Valley	CA	93012
Phone	**Title**		
818-554-4088	Owner		
Description of Duties			
Rental property management			

Business Name			From - To (MM/YY – MM/YY)
Sandhill Village LLC			07/2019 - Current
Business Address	**City**	**State**	**Zip**
5400 Atlantis Court	Moorpark	CA	93021
Phone	**Title**		
818-554-4088	Owner		
Description of Duties			
No active duties - this entity owns a vacant parcel of land			

Business Name			From - To (MM/YY – MM/YY)
Pintail Capital Group LLC			01/2015 - Current
Business Address	**City**	**State**	**Zip**
13241 HIghway 155 South	Tyler	TX	75703
Phone	**Title**		
903-581-8544	Shareholder		
Description of Duties			
No active participation, investment only			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Amidon Partners Ltd			02/2014 - Current
Business Address	City	State	Zip
13241 Highway 155 South	Tyler	TX	75703
Phone	Title		
903-581-8544	Shareholder		
Description of Duties			
No active participation, investment only			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/22/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luca Jacobellis
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/24
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Ventura

I, Luca Jacobellis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/22/24
Date

Subscribed and Sworn to before me this 22 day of November 2024

Becky R Jensen
Notary Public Signature

BECKY R. JENSEN
Notary Public - California
Ventura County
Commission # 2450889
My Comm. Expires Jun 20, 2027

(Seal)

Nevada State Licensing Application
Additional Information – Section 9

Directors & Officers:

- Jennifer Jacobellis – Owner, President/CEO
- Luca Jacobellis – Owner, Secretary

California Secretary of State – Certificate of Good Standing (Attached)

California Dept. of Public Health - HMDR License #115701 (Attached)

Proof of Insurance – Commercial General Liability policy #81-SBA-BD1Y9Z (Attached Cert of Liability Insurance)

Personal History Record Applications (Attached)

- Jennifer Jacobellis
- Luca Jacobellis

MDEG Administrator Application (Attached)

- Jennifer Jacobellis

4F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Cardinal Health 200, LLC

Physical Address: 7461 Metro Air Parkway

City: Sacramento State: CA Zip: 95835

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 530-406-3600 Website: www.cardinalhealth.com

Name of Designated Representative (DR): William Grey, Jr.

Licensing Company Email: licensure@cardinalhealth.com DR Email: william.greyjr@cardinalhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		■ Others: 3PL - Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

See Attached Explanation

K Chhd

Original Signature (electronic, copies or stamps not accepted)

11/13/24

Date

CardinalHealth

December 6, 2024

Dave Wuest, Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

RE: Explanation of Disciplinary History
Cardinal Health 200, LLC – Sacramento, CA

Dear Mr. Wuest:

This letter is provided in conjunction with our affirmative response to Question 3 on our application for Wholesale. We have a few matters to disclose based on our parent company, Cardinal Health, Inc. Please note that the facility that is the subject of this application does not have any disciplinary history to disclose.

On September 24, 2020, Cardinal Health finalized a settlement agreement with the Colorado Board of Pharmacy and paid a fine of $1,150. This settlement was regarding the failure of our Denver, Colorado distribution center to timely notify the Board of a change in that distribution center's designated representative.

Cardinal Health's pharmaceutical distribution center in Valencia, California entered into a settlement agreement with the California Board of Pharmacy in April 2019. As a condition of that settlement, the California Wholesale license for our Valencia distribution center was on probation from April 3, 2019, through April 2, 2021. This agreement resulted from the Valencia distribution center making sales to a customer between 2012 and 2014 and the failure to receive a pharmacist's signature on several deliveries in that same time frame.

Additionally, on March 11, 2019, Cardinal Health's Wheeling, West Virginia, distribution center entered into a settlement agreement with the Ohio Board of Pharmacy regarding the security and storage of drugs while those drugs were being distributed to the customer. This issue involved Ohio Board of Pharmacy inspectors manipulating our totes in such a way as to be able to retrieve a bottle out of a strapped/sealed tote. This occurred on several occasions all while the totes were in the custody of our delivery drivers or pharmacies. An inspector also witnessed a delivery vehicle door that was not locked and secured appropriately. Cardinal Health agreed to pay a monetary penalty of $5,000.

As previously reported, on May 15, 2012, Cardinal Health entered into a settlement agreement with the U.S. Drug Enforcement Administration ("DEA") regarding Cardinal Health's registration to distribute controlled substances from our Lakeland, Florida facility. On February 3, 2012, DEA served an Order to Show Cause and Immediate Suspension of Registration (the "Order") on Cardinal Health's Lakeland, Florida distribution center. In the Order, DEA alleged that the Lakeland facility "failed to maintain effective controls against the diversion of controlled substances" and "failed to detect and report suspicious orders of oxycodone by its pharmacy customers." In particular, DEA identified four retail pharmacies located in Florida that were serviced by the Lakeland facility and alleged that "[n]otwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted...." Importantly, these allegations did not involve any diversion of controlled substances from Cardinal's facility.

Under the settlement agreement, the Lakeland facility's DEA registration was suspended for two years from the date of the settlement agreement. On May 21, 2014, the suspension was lifted and the DEA reinstated Lakeland's registration. On December 23, 2016, Cardinal Health reached a nationwide settlement with the federal government, resolving the outstanding civil penalty portion of this May 15, 2012, administrative settlement with the DEA. Under this civil settlement, Cardinal Health has agreed to pay $44 million to the Department of Justice (DOJ) to resolve this matter. The DOJ, including the DEA and the United States Attorneys' Offices for the Middle District of Florida, the Southern District of New York, the District of Maryland, and the Western District of Washington and all other districts across the country have also agreed to take no further administrative or civil action on these and related matters. In addition, Cardinal Health has reached an agreement with the State of West Virginia regarding the company's distribution of controlled substances in that state between 2007 and 2012. While Cardinal Health denies the allegations, it agreed to pay West Virginia $20 million to resolve issues and release the company from further actions.

In 2014, the Boards of Pharmacy in both California and Georgia took derivative action based upon the DEA settlement. The Georgia Board fined the Lakeland facility $500 in administrative fees, and the California Board fined the facility $1,505 in investigative fees. Both fees were paid to the respective Boards.

In September 2013, Cardinal Health's distribution center located in Ontario, California, received a citation involving prescription device deliveries being made to an unauthorized customer; the facility paid the fine of $5,000.00 and the matter was closed. In July 2014, the State of Michigan Department of Licensing and Regulatory Affairs (LARA) took derivative action against the Ontario, CA, facility based upon the action described above. LARA issued a Consent Order and fined the Ontario facility $500. Cardinal Health paid the fine to LARA on July 9, 2014.

If you have any questions, Cory Kopitzke, Assistant General Counsel, Regulatory at Cory.Kopitzke01@cardinalhealth.com.

Sincerely,

Keegan Chamberlain
Director, Global Logistics Quality Management

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Baxter Healthcare Corporation
Address: One Baxter Parkway City: Deerfield State: IL Zip: 60015
Name: Vantive US Healthcare LLC
Address: One Baxter Parkway Building 6 City: Deerfield State: IL Zip: 60015
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Allegiance Corporation (Parent Company of Cardinal Health 200, LLC)
Corporation Name: Cardinal Health Inc. (Ultimate Holding Company)
Mailing Address: 7000 Cardinal Place
City: Dublin State: OH Zip: 43017
Telephone: 614-757-5000 Email: licensure@cardinalhealth.com
Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983	SEC Registration Number: 721371	Stock Exchange Symbol: CAH

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/a
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/a
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/a
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cardinal Health 200, LLC

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/13/24

Date

Board Use Only	Date Received: 11/27/24	Amount: $1000-CK 10913161

CardinalHealth

7461 Metro Air Parkway
STE 300
Sacramento, California 95835

Officer Name	Title	Business Address	Business Phone Number	Email Address
Stephen Michael Mason	CEO, Medical Segment	7000 Cardinal Place, Dublin, OH 43017	614-757-6292	Steve.Mason@cardinalhealth.com
Keegan David Chamberlain	Director, Quality Management	7000 Cardinal Place, Dublin, OH 43017	614-553-4640	Keegan.Chamberlain@cardinalhealth.com
Julie Erin Webb	VP, Quality Management	7000 Cardinal Place, Dublin, OH 43017	614-757-6343	julie.webb@cardinalhealth.com
John Henry Martin Jr.	SVP, Tax	7000 Cardinal Place, Dublin OH 43017	614-757-3769	john.martin03@cardinalhealth.com
Brent Mathew Withrow	Assistant Treasurer	7000 Cardinal Place, Dublin, OH 43017	614-757-6977	brent.withrow@cardinalhealth.com

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Cardinal Health - Medical Distribution,
Quality & Regulatory Affairs
7000 Cardinal Place
Dublin OH 43017
cardinalhealth.com
614.553.3076 tel

licensure@cardinalhealth.com email

CardinalHealth

Top 4 Corporation Shareholders

Name	Percentage of Ownership
Vanguard Fiduciary Trust Co.	12.65 %
BlackRock Advisors LLC	9.478 %
STATE STREET CORPORATION	5.600 %
Geode Capital Management LLC	2.359 %

Department of State: Division of Corporations

Allowable Characters

HOME

View Search Results

Entity Details

File Number:	**2610958**	Incorporation Date / Formation Date:	**6/26/1996** (mm/dd/yyyy)
Entity Name:	**CARDINAL HEALTH 200, LLC**		
Entity Kind:	**Limited Liability Company**	Entity Type:	**General**
Residency:	**Domestic**	State:	**State:**
Status:	Good Standing	Status Date:	6/2/2021

REGISTERED AGENT INFORMATION

Name:	**THE CORPORATION TRUST COMPANY**		
Address:	**CORPORATION TRUST CENTER 1209 ORANGE ST**		
City:	**WILMINGTON**	County:	**New Castle**
State:	**DE**	Postal Code:	**19801**
Phone:	**302-658-7581**		

Back to Entity Search | Email Status

For help on a particular field click on the Field Tag to take you to the help area.

BOARD OF PHARMACY

LICENSING DETAILS FOR: TPL 1454

NAME: CARDINAL HEALTH 200 LLC

LICENSE TYPE: THIRD-PARTY LOGISTICS PROVIDER

LICENSE STATUS: CLEAR

ADDRESS

7461 METRO AIR PARKWAY SUITE 300
SACRAMENTO CA 95835
SACRAMENTO COUNTY

ISSUANCE DATE

SEPTEMBER 3, 2024

EXPIRATION DATE

DECEMBER 15, 2024

CURRENT DATE / TIME

SEPTEMBER 4, 2024
8:20:33 AM

LICENSE RELATIONSHIPS

NAME: GREY JR, WILLIAM

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (THIRD-PARTY LOGISTICS PROVIDER)

LICENSE NUMBER: 40326 **PRIMARY STATUS:** CLEAR

CardinalHealth™

June 30, 2024

To whom it may concern:

This is a declaration and confirmation by Cardinal Health, Inc. and its subsidiaries exclusively that:

Cardinal Health is self-insured for products, completed operations liability and pharmacist professional liability. You will not be named as additional insured for any of the self-insured retention limits of the product liability, completed operations liability and pharmacist professional liability coverages. Cardinal Health's self-insurance is backed by its financial strength documented in financial statements found at www.cardinalhealth.com. The existence of self-insurance within Cardinal Health's insurance program does not change any contractual obligation we may have, and shall not be deemed to exceed the scope of coverage and/or limits required, under our written contract or agreement with you.

As respects the Automobile Liability, Automobile Physical Damage, Comprehensive and Collision coverage is self-insured for all owned and leased vehicles.

Please direct any questions or concerns to GMB-DUB-RiskManagement@cardinalhealth.com.

Denise Johnston
Director, Risk Management

JPK/as

enc.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 05/31/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. Cincinnati OH Office 8044 Montgomery Road Suite 405 Cincinnati OH 45236-2919 USA	PHONE (A/C, No, Ext): (866) 283-7122	FAX (A/C, No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Cardinal Health, Inc. 7000 Cardinal Place Attn: Suzanne Cochran Dublin OH 43017 USA	INSURER A: Greenwich Insurance Company	22322
	INSURER B: XL Insurance America Inc	24554
	INSURER C: XL Specialty Insurance Co	37885
	INSURER D: Indian Harbor Insurance Company	36940
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570105992993 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			RGD943716719	06/30/2024	06/30/2025	EACH OCCURRENCE	$5,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
	X Liquor Liability Included						MED EXP (Any one person)	
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$5,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$5,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	Excluded
							Liquor Liability Lim	Included
A	AUTOMOBILE LIABILITY			RAD943716819	06/30/2024	06/30/2025	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / in SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB X OCCUR			US00092147LI24A	06/30/2024	06/30/2025	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE			SIR applies per policy terms & conditions			AGGREGATE	$5,000,000
	DED X RETENTION						Products/Completed O	Excluded
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			RWD943512519 (AOS)	06/30/2024	06/30/2025	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		RWR943512619 (WI)	06/30/2024	06/30/2025	E.L. EACH ACCIDENT	$5,000,000
							E.L. DISEASE-EA EMPLOYEE	$5,000,000
							E.L. DISEASE-POLICY LIMIT	$5,000,000
D	E&O - Professional Liability - Primary			RGD943797705 E&O SIR applies per policy terms & conditions	06/30/2024	06/30/2025	Loss Limit	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Cardinal Health, Inc.
7000 Cardinal Place
Dublin OH 43017 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc

Holder Identifier :

Certificate No : 570105992993

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AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER: See Certificate Number: 570105992993	
CARRIER: See Certificate Number: 570105992993 / NAIC CODE	EFFECTIVE DATE

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
C		N/A		RWR300142406 (AK)	06/30/2024	06/30/2025		
	OTHER							
C	Excess Workers Compensation			RWE943514319 Xs Work Comp – OH SIR applies per policy terms & conditions	06/30/2024	06/30/2025	EL Each Accident	$4,500,000
							EL Disease - Ea Empl	$4,500,000

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

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FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Evidence of Coverage

As respects the Commercial General Liability Policy:
Additional Insured Managers or Lessors of Premises : as required by written contract
Additional Insured Owners, Lessees or Contractors - Scheduled Persons or Organization : as required by written contract
Coverage provided to the additional insured is required by a contract or agreement, the insurance afforded to such additional insured will not be broader than that which you are required by the contract or agreement to provide for such additional insured and shall not increase the applicable Limits of Insurance

As respects the Automobile Liability Policy:
Coverage symbol 1 (Any Auto) applies to Automobile Liability which includes coverage for Hired / Non-Owned Autos
Lessor - Additional Insured: all leased autos.
The policy will pay as interest may appear, you (Cardinal Health) and the lessor named in this endorsement for "loss" to a "leased auto".
Additional Insured Where Required under Written Contract or Agreement Endorsement

As respects General Liability, Automobile Liability, and Workers Compensation Policies:
Waiver of Subrogation is permitted as required by written contract or agreement executed prior to loss and in accordance with the terms, conditions and exclusions of the applicable policies.

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AGENCY CUSTOMER ID: 570000070825
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ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
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ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

Named Insured Listing for June 30, 2024 - June 30, 2025 includes but is not limited to the following:
A+ Secure Packaging, LLC
Abilene Nuclear, LLC
Acuity GPO, LLC
Aero-Med, LLC
Allegiance (BVI) Holding Co. Ltd.
Allegiance Corporation
Allegiance Healthcare (Labuan) Pte. Ltd.
Allegiance I, LLC
Allegiance Labuan Holdings Pte. Ltd.
C. International, Inc.
Cardinal Distribution Holding Corporation - I
Cardinal Distribution Holding Corporation - II
Cardinal Health (Shanghai) Medical Devices Co., Ltd.
Cardinal Health 100, LLC
Cardinal Health 104 LP
Cardinal Health 105, LLC
Cardinal Health 107, LLC
Cardinal Health 108, LLC
Cardinal Health 110, LLC
Cardinal Health 112, LLC
Cardinal Health 113, LLC
Cardinal Health 114, Inc.
Cardinal Health 115, LLC
Cardinal Health 116, LLC
Cardinal Health 118, LLC
Cardinal Health 119, LLC
Cardinal Health 121, LLC
Cardinal Health 122, LLC
Cardinal Health 123, LLC
Cardinal Health 124, LLC
Cardinal Health 125, LLC
Cardinal Health 126, LLC
Cardinal Health 127, Inc.
Cardinal Health 128, LLC
Cardinal Health 130, LLC
Cardinal Health 131, LLC
Cardinal Health 132, LLC
Cardinal Health 133, Inc.
Cardinal Health 134, LLC
Cardinal Health 135, LLC
Cardinal Health 2, LLC
Cardinal Health 200, LLC
Cardinal Health 201 Canada L.P.
Cardinal Health 201, LLC
Cardinal Health 215, LLC
Cardinal Health 222 (Thailand) Ltd.
Cardinal Health 23 Funding, LLC
Cardinal Health 23, LLC
Cardinal Health 242, LLC
Cardinal Health 247, Inc.

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AGENCY CUSTOMER ID: 570000070825
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ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Cardinal Health 249, LLC
Cardinal Health 3, LLC
Cardinal Health 414, LLC
Cardinal Health 418, Inc.
Cardinal Health 5, LLC
Cardinal Health 524, LLC
Cardinal Health 529, LLC
Cardinal Health 6, Inc.
Cardinal Health 7, LLC
Cardinal Health 8, LLC
Cardinal Health Australia 503 Pty Ltd.
Cardinal Health Austria 504 GmbH
Cardinal Health Belgium 505 BV
Cardinal Health Canada Inc.
Cardinal Health Capital Corporation
Cardinal Health Cardiology Solutions, LLC
Cardinal Health Chile Limitada
Cardinal Health Colombia S.A.S.
Cardinal Health Commercial Technologies, LLC
Cardinal Health Corporate Solutions, LLC
Cardinal Health D.R. 203 II Ltd.
Cardinal Health do Brasil Ltda.
Cardinal Health Finance
Cardinal Health Finland Oy
Cardinal Health Foundation
Cardinal Health France 506 SAS
Cardinal Health Funding, LLC
Cardinal Health Germany 507 GmbH
Cardinal Health Germany Manufacturing GmbH
Cardinal Health Holding International, Inc.
Cardinal Health Holdings Hungary Kft.
Cardinal Health International India Pvt. Ltd.
Cardinal Health International Philippines, Inc.
Cardinal Health IPS, LLC
Cardinal Health Ireland 419 Designated Activity Company
Cardinal Health Ireland 508 Limited
Cardinal Health Ireland Manufacturing Limited
Cardinal Health Ireland Unlimited Company
Cardinal Health Italy 509 S.r.l.
Cardinal Health K.K.
Cardinal Health Korea Limited
Cardinal Health Luxembourg 420 S.a.r.l.
Cardinal Health Luxembourg 522 S.a.r.l.
Cardinal Health Malaysia 211 Sdn. Bhd.
Cardinal Health Malta 212 Limited
Cardinal Health Managed Care Services, LLC
Cardinal Health Mexico 514 S. de R.L. de C.V.
Cardinal Health Middle East FZ-LLC
Cardinal Health MPB, Inc.
Cardinal Health Napoleon Holding, LLC
Cardinal Health Netherlands 502 B.V.
Cardinal Health Netherlands 525 Cooperatie U.A.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Cardinal Health P.R. 120, Inc.
Cardinal Health P.R. 218, Inc.
Cardinal Health P.R. 220, LLC
Cardinal Health P.R. 436, Inc.
Cardinal Health Panama, S. de R.L.
Cardinal Health Pharmaceutical Contracting, LLC
Cardinal Health Pharmacy Services, LLC
Cardinal Health Singapore 225 Pte. Ltd.
Cardinal Health Spain 511 S.L.
Cardinal Health Switzerland 515, GmbH
Cardinal Health Systems, Inc.
Cardinal Health Technologies Switzerland GmbH
Cardinal Health Technologies, LLC
Cardinal Health U.K. 418 Limited
Cardinal Health U.K. 432 Limited
Cardinal Health U.K. Holding Limited
Cardinal Health U.K. International Holding LLP
Cardinal Health, Inc.
Cardinal MED Equipment Consulting (Shanghai) Co., Ltd.
Cirpro de Delicias S.A. de C.V.
Clinic Pharmacies III, LLC
Clinic Pharmacies, LLC
Convertors de Mexico S.A. de C.V.
Cordis Corporation
Cornerstone Rheumatology LP
Covidien Manufacturing Solutions, S.A.
Dutch American Manufacturers II (D.A.M. II) B.V.
Ellipticare, LLC
EPIC Insurance Company
Especialidades Medicas Kenmex S.A. de C.V.
Experience East, LLC
Flexible Stenting Solutions, LLC
GastroGPO, LLC
Gastrologix, LLC
Generic Drug Holdings, LLC
Griffin Capital, LLC
HDG Acquisition, LLC
imgRx Healdsburg, Inc.
imgRx Salud, Inc.
imgRx SJ Valley, Inc.
imgRx SLO, Inc.
imgRx Sonoma, Inc.
InnerDyne Holdings, Inc.
Innovative Therapies, LLC
Instant Diagnostic Systems, Inc.
InteCardia-Tennessee East Catheterization, LLC
ITI Sales, LLC
Kendall-Gammatron Limited
Killilea Development Company, Ltd.
Kinray I, LLC
KPR U.S., LLC
Leader Drugstores, Inc.
Ludlow Technical Products Canada, Ltd.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
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POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Marin Apothecaries
Medicap Pharmacies Incorporated
Medicine Shoppe Capital Corporation
Medicine Shoppe International, Inc.
Medicine Shoppe Internet, Inc.
Mediquip Sdn. Bhd.
MosaicGPO, LLC
mscripts Holdings, LLC
mscripts, LLC
Nautic Specialty Networks VIII-A Bocker, Inc.
Navista Investments, LLC
Navista Network Holding, LLC
Navista Network, LLC
One Cloverleaf, LLC
Owen Shared Services, Inc.
Pharmacy Operations Of New York, Inc.
Pharmacy Operations, Inc.
Physicians Purchasing, Inc.
Pinnacle Intellectual Property Services, Inc.
Pinnacle Intellectual Property Services-International, Inc.
Precision Point Specialty, LLC
Quiroproductos de Cuauhtemoc S. de R.L. de C.V.
RainTree Administrative Services, LLC
RainTree Care Management, LLC
RainTree GPO, LLC
Red Oak Sourcing, LLC
Renal Purchasing Group, LLC
RGH Enterprises, LLC
RT Oncology Services Corporation
Rxealtime, Inc.
Scalamed (US), Inc.
ScalaMed Pty Ltd
Sierra Radiopharmacy, L.L.C.
SN Buyer, LLC
SN Funding, LLC
SN Intermediate, Inc.
SOAR Network, LLC
Sonexus Health Access & Patient Support, LLC
Sonexus Health Distribution Services, LLC
Sonexus Health Financial Solutions, LLC
Sonexus Health Pharmacy Services, LLC
Sonexus Health, LLC
Specialty Networks Consulting, LLC
Specialty Networks Research, LLC
Specialty Networks Urology Registry, LLC
Specialty Networks, LLC
The Harvard Drug Group, L.L.C.
Traverse GPO, LLC
United Rheumatology NY IPA I, LLC
United Rheumatology, LLC
UR Nice, LLC
UroGPO, LLC
Velocare, LLC
Wavemark Cyprus Pvt. Ltd.
Wavemark Lebanon Offshore s.a.l.
Wavemark, Inc.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Cardinal Health 200, LLC — MDEG License # (if applicable): New App

Physical Address: 7461 Metro Air Parkway, Suite 300

City: Sacramento — State: CA — Zip: 95835

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin — State: OH — Zip: 43017

Telephone: 530-406-3600 — Website: www.cardinalhealth.com

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: William — Middle: — Last: Grey Jr.

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: — Sex: ☑ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Elk Grove — State: CA — Zip: 95758

Telephone: [redacted] — Email: william.greyjr@cardinalhealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Sacramento State University		1995	
Address	**City**	**State**	**Zip**
6000 J Street	Sacramento	Ca	95819
Diploma/Degree obtained, if any			
B.S. in Criminal Justice			

School Name		From - To (MM/YY – MM/YY)	
Chadsey High School		1980 - 1984	
Address	**City**	**State**	**Zip**
5335 Martin	Detroit	Mich	48210
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1999-present	[redacted]	Elk Grove	Ca	95758
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health 200, LLC			2013- Present	
Business Address		**City**	**State**	**Zip**
700 Vaughn Road		Dixon	CA	95620
Phone	**Title**		**Number of Employed Hours**	
530-406-3600	Outbound Supervisor		1500 +	
Description of Duties				
Coordinates and supervises the daily activities of the operations of distributing prescription drugs and devices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/a

Original Signature (electronic, copies or stamps not accepted)

10/30/2024
Date

I, William Grey,Jr. **, certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. (W) Have a high school diploma or its equivalent;
2. (W) Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. (W) Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. (W) Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Grey,Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2024
Date

Board Use Only	Date Received: _____

Cardinal Health - Medical Distribution,
Quality & Regulatory Affairs
7000 Cardinal Place
Dublin OH 43017
cardinalhealth.com
614.553.3076 tel

licensure@cardinalhealth.com email

CardinalHealth

Cardinal Health 200, LLC
7461 Metro Air Parkway STE 300
Sacramento, CA 95835

Employee List

William Grey,Jr, *Supervisor* – Designative Representative
Romeyn Webb, *Director, Operations Mgt*
David Wasser, *Sr Specialist, Quality Mgmt*
David Riddle, *Manager, Operations Mngmt*

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 6, 2024

Cardinal Health, Inc.
(Exact Name of Registrant as Specified in Charter)

Ohio	1-11373	31-0958666
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7000 Cardinal Place, Dublin, Ohio 43017
(Address of Principal Executive Offices) (Zip Code)

(614) 757-5000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares (without par value)	CAH	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 6, 2024 and September 8, 2024, respectively, Steven K. Barg and Sujatha Chandrasekaran, both members of the Board of Directors (the "Board") of Cardinal Health, Inc. (the "Company") since 2022, informed the Company that they have decided not to stand for re-election to the Board when their terms expire at the 2024 annual meeting of shareholders. Both Mr. Barg and Ms. Chandrasekaran will continue to serve as directors until the 2024 annual meeting of shareholders. Mr. Barg and Ms. Chandrasekaran have each indicated that their decisions are not the result of any disagreement with the Company on any matter relating to the Company's operations, policies, or practices.

Both Mr. Barg and Ms. Chandrasekaran were originally appointed as members of the Board pursuant to a cooperation agreement entered into on September 5, 2022 between the Company and Elliott Associates, L.P. and Elliott International, L.P. (together, "Elliott"). As Elliott's investor designee to the Board, Mr. Barg was a member of the Board's Business Review Committee that was chartered to conduct a review of the Company's strategy, portfolio, capital allocation framework, and operations during its tenure. The Business Review Committee sunsetted on July 15, 2024. Mr. Barg currently serves on the Board's Governance and Sustainability Committee. Ms. Chandrasekaran is a member of the Board's Audit and Risk Oversight Committees. The Company thanks Mr. Barg and Ms. Chandrasekaran for their service and for their valuable contributions during their tenure on the Board.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cardinal Health, Inc.
(Registrant)

Date: September 9, 2024

By: /s/ Jessica L. Mayer
Name: Jessica L. Mayer
Title: Chief Legal and Compliance Officer

4G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

[redacted]

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: G1 Therapeutics, Inc.

Physical Address: 700 Park Offices Drive, Suite 200

City: Research Triangle Park State: NC Zip: 27709

Mailing Address (if different from physical address): 700 Park Offices Drive, Suite 200, P. O. Box 110341

City: Research Triangle Park State: NC Zip: 27709

Telephone: 919-213-9835 Website: https://www.g1therapeutics.com/

Name of Designated Representative (DR): Jonathan Lindberg

Licensing Company Email: licensing@g1therapeutics.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors		☒ Others: Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	x	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
9/10/2021	6/16/2022			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2021-001195		Alaska Board of Parmacy		
Reason/Charge				
Violation of 12 AAC 52,610(d)(1)				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Joshua Franklin		n/a		
Name of Business/Industry/Entity				
Pharmacosmos Therapeutics, Inc				

Provide explanation below:

Parent Company (owner) Pharmacosmos Therapeutics, Inc was disciplined by AK and issued a Civil Fine of for failure to provide properly timed notification of change in Facility Manager.

Original Signature (electronic, copies or stamps not accepted)

10-15-2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
09/03/2024	10/2/2024	NJ	MORRISTOWN	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
24-266	Kansas Board of Pharmacy

Reason/Charge
FAILURE TO RENEW & DISTRIBUTION WHILE EXPIRED

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
JOSHUA FRANKLIN	n/a

Name of Business/Industry/Entity
Pharmacosmos Therapeutics, Inc

Provide explanation below:

KS ISSUED A SUMMARY ORDER FOR A DISCIPLINARY FINE IN THE AMOUNT OF $1920.00. PHARMACOSMOS THERAPEUTICS INC PAID THE FINE & THE LICENSE HAS BEEN RENEWED. THE MATTER WAS CONFIRMED CLOSED ON 10/2/2024

Original Signature (electronic, copies or stamps not accepted)

10/3/2024
Date

Disciplinary Explanation

G1 Therapeutics, Inc has never received a disciplinary order/fine/other.

The parent company of G1 Therapeutics, Inc has been issued discipline by the state of Alaska and the state of Kansas. Attached you will find the related documentation for the following events:

On 9/10/2021 Pharmacosmos Therapeutics, Inc (G1's parent company) received a Civil Fine (Case No. 2021-001195) for the failure to provide notification of change in Facility Manager within the required timeframe. This was a violation of 12 AAC 52.610(d)(1); Pharmacosmos signed the civil order and paid the fine of Three-Hundred Dollars ($300.00) to the AK State Board of Pharmacy to resolve the matter. No further action is pending. The matter was resolved on 16th, June 2022.

On 9/3/2024 Pharmacosmos Therapeutics, Inc (G1's parent company) received a Summary Order (Case No. 24-266) for late renewal and shipments entering KS while the license was expired. This was a violation of K.S.A. 65-1643(g) and Kansas Board of Pharmacy issued a fine of One-Thousand Nine Hundred and Twenty Dollars ($1,920.00). Pharmacosmos has paid this fine and no further action is required. Kansas Board of Pharmacy has confirmed this matter closed and the license has renewed. No further action is pending. The matter was confirmed resolved on 2nd of October 2024.

There are no other known disciplinary investigations at this time.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2021-001195

I, Joshua Franklin, as an agent for Pharmacosmos Therapeutics Inc., admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of my Out-Of-State Wholesale Drug Distributer License No. 160916, and over this Imposition of Civil Fine.

1. On September 10, 2021, we appointed a new facility manager. On November 04, 2021, the Board received our Change of Facility Manager form with the new facility manager notification; 56 days after the facility manager change occurred. **This is a violation of 12 AAC 52.610(d)(1).**

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.610(d)(1). We are agreeing to this Imposition of a Civil Fine of three hundred dollars ($300) in cash, certified check, or money order payable to the **"State of Alaska"** within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

Joshua Franklin, Chief Commercial Officer
Name/Title, Respondent

April 11, 2022
Date

SUBSCRIBED AND SWORN TO before me this 11th day of APRIL, 2022, at Morristown, NJ, Alaska.

SEAL

Notary Public in and for Alaska

CLP
EP

Janet D. Castellacci'o
Notary Printed Name
My commission expires: 1-13-27

Janet D Castellacci'o

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Pharmacosmos Therapeutics Inc.)
)
Respondent)
Case No. 2021-001195

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2021-001195, regarding license number 160916, for failure to timely notify the Board of a Facility Manager change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 16th day of June, 2022, at Soldotna, Alaska.

ALASKA BOARD OF PHARMACY

By: _____
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 3, 2024

Pharmacosmos Therapeutics Inc
120 Headquarters Plaza East Tower 6th Floor
Morristown NJ 07960

RE: Case No. 24-266

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $1,920. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 24-266
Pharmacosmos Therapeutics Inc	)	
	)	
Registration Number 4-111418	)	

SUMMARY ORDER

NOW, on this 3rd day of September, 2024, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Pharmacosmos Therapeutics Inc. ("Respondent"), for late renewal of the non-resident manufacturer registration issued by the Board.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 4-111418 which entitles Respondent to operate as a non-resident manufacturer in the State of Kansas ("Respondent's Registration").

2. On July 1, 2024, Respondent's Registration expired for nonrenewal.

3. On August 5, 2024, the Board received Respondent's application for late renewal registration as a non-resident manufacturer in the State of Kansas ("Respondent's Application").

4. In conjunction with Respondent's Application, Respondent provided requested copies of shipping records for products shipped into Kansas. Respondent reported shipping into

Kansas on 21 unique days during the period of expiration.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f)(6), the Board may take action against the application of any manufacturer provider upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(g), it shall be unlawful for any person to manufacture any drugs or devices without first obtaining a registration from the Board.

4. Respondent's act of shipping into Kansas with an expired registration and no current manufacturer registration is a violation of K.S.A. 65-1643(g) and is a basis to take action against Respondent's Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent's Application is hereby GRANTED but Respondent is ordered to pay a fine to the Board in the amount of $1,920. Respondent has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing

is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

9/3/2024
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 3rd day of September, 2024, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Parmacosmos Therapeutics Inc
120 Headquarters Plaza East Tower 6th Floor
Morristown NJ 07960

Kansas Board of Pharmacy Staff

PHARMACOSMOS
THERAPEUTICS

Date: September 11, 2024

To:

Kansas State Board of Pharmacy

800 SW Jackson

Suite 1414

Topeka, KS 66612-1244

Subject: Pharmacosmos Therapeutics Inc. License # 4-111418

Please see attached check payment of $1920.00 in connection with Case # 24-266 for renewal of KS State Board of Pharmacy License # 4-111418

Feel free to reach out if you have any questions.

Thank you,

Fatima Majid

Manager Administrative Operations

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CHECK AMOUNT

PHARMACOSMOS THERAPEUTICS INC 10-19
120 HEAD QUARTERS PLAZA
EAST TOWER, 6TH FLOOR
MORRISTOWN, NJ 07960

September 11, 2024

PAY TO THE ORDER OF Kansas State Board of Pharmacy

$ $1,920.00

****ONE THOUSAND NINE HUNDRED TWENTY AND 0/100 US DOLLARS DOLLARS

VALID VALID

AUTHORIZED SIGNATURE

MEMO

Kansas State Board of Pharmacy
800 SW Jackson Street
Suite 1414
Topeka, KS 66612
USA [redacted]

Details on Back. Security Features Included

PHARMACOSMOS THERAPEUTICS INC 11410

Document No.	Document Date	Posting Description	Amount	Discount	Net Amount
BR-	9/10/2024	Invoice 10693	1,920.00	0.00	1,920.00

Total **1,920.00**

PHARMACOSMOS THERAPEUTICS INC 11410

Document No.	Document Date	Posting Description	Amount	Discount	Net Amount
BR-	9/10/2024	Invoice 10693	1,920.00		1,920.00

Total **1,920.00**

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Pharmacosmos Therapeutics Inc.

Corporation/Organization Name: G1 Therapeutics, Inc.

Mailing Address: 700 Park Offices Drive, Suite 200, P. O. Box 110341

City: Research Triangle Park State: NC Zip: 27709

Telephone: 9733937425 Email: [redacted]

Contact Person Name: Joshua Franklin

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

G1 Therapeutics, Inc.
Facility Name

Joshua Franklin
Print Name of Authorized Person Submitting Application

Joshua Franklin
Original signature of Authorized Person (copies or stamps not accepted)

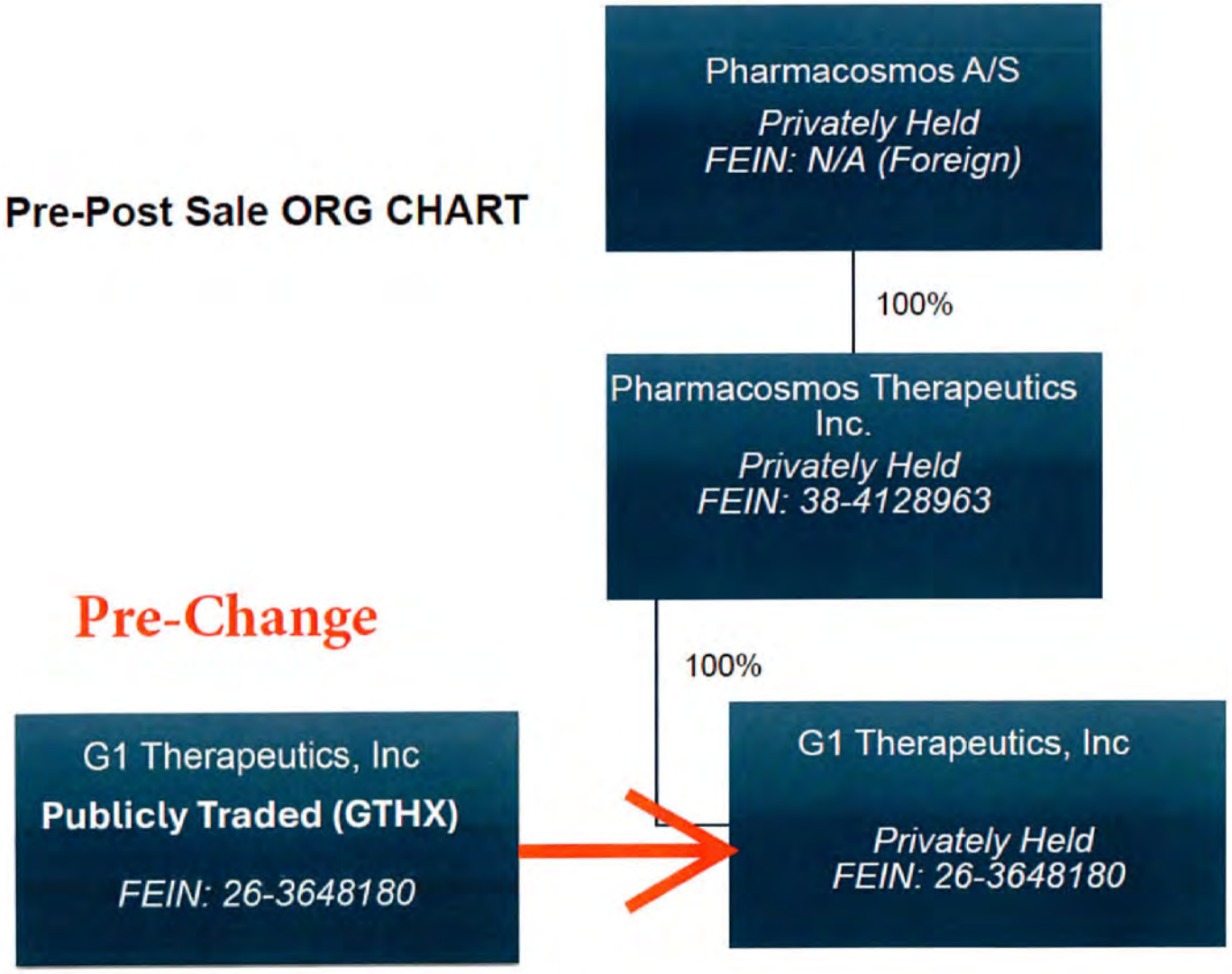
10/3/2024
Date

Board Use Only	Date Received: 10/21/24	Amount: $1000 ck 2425

G1 Therapeutics Inc. – Ownership

Post-Change

Pre-Post Sale ORG CHART



Pre-Change

Copyright Pharmacosmos

PHARMACOSMOS

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov

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Current through October 9, 2024

You have searched Finished drug products

Search Results: *'G1 Therapeutics'*

Back to Search Page

Keyword Search Reset Showing 1 to 1 of 1 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date
COSELA	73462-101-01	300mg/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA214200	G1 Therapeutics, Inc.	73462-101	trilaciclib	TRILACICLIB DIHYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/12/202

Previous 1

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

FDA Archive About FDA Accessibility

Visitor Information Website Policies / Privacy No FEAR Act

FOIA HHS.gov USA.gov

Vulnerability Disclosure Policy

Contact FDA FDA 1-888-INFO-FDA (1-888-463-6332)

Description of Operations

G1 Therapeutics, Inc. is a VirtualManufacturer. G1 Therapeutics, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors by their Third-Party Logistics Provider, Integrated Commercialization Solutions, LLC , who is licensed to ship pharmaceutical products into your state.

G1 Therapeutics, Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

Labeler Code: 73462

Contract Manufacturer Information: Patheon manufactures G1 Therapeutics, Inc.'s product and packages finished product. At no time does Patheon own the product, contract with G1 Therapeutics, Inc.'s customers, invoice, nor sell a G1 Therapeutics, Inc. product. G1 Therapeutics, Inc.'s products are not Controlled Substances.

Patheon Manufacturing Services LLC
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
FDA Establishment Number: 1018495

Third Party Logistic information:
Integrated Commercialization Solutions, LLC
167 International Blvd,
Brooks, KY 40109
Contact Person: Bonnie Diep
Phone: 469-219-7133
Email: [redacted]

Company Information

G1 Therapeutics, Inc.
700 Park Offices Drive, Suite 200
Research Triangle Park, NC, 27709
919-213-9835
https://www.g1therapeutics.com/
licensing@g1therapeutics.com

FEIN: 26-3648180
State of Formation: DE
Date Incorporated: 5/19/2008
File Number: 4549681

Ownership Information

G1 Therapeutics, Inc. is 100% owned by Pharmacosmos Therapeutics Inc.

Parent Company Address: 120 Headquarters Plaza - East Tower 6th Floor
Parent Company Phone: (973) 393-7425
Parent Company FEIN: 38-4128963

Officers

Joshua Franklin, President
Business Address: 120 Headquarters Plaza, East Tower, 6th Flr, Morristown, NJ 07960
Business Phone: (973) 393-7425

John Deno, Corporate Secretary / General Counsel
Business Address: 120 Headquarters Plaza, East Tower, 6th Flr, Morristown, NJ 07960
Business Phone: 732-614-9537

Katharina Russo, Treasurer
Business Address: 120 Headquarters Plaza, East Tower, 6th Flr, Morristown, NJ 07960
Business Phone: 862-345-0331

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "G1 THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4549681 8300

SR# 20242402352

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203546505

Date: 05-23-24

2024

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1686

LICENSE/CERTIFICATE: Virtual Manufacturer
TYPE
Expiration Date 12/31/2024

ENSEE G1 Therapeutics, Inc.
RTIFICATOR 700 Park Offices Drive, Suite 200
Research Triangle Park NC 27709

LICENSED 2024 NORTH CAROLINA

IIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJG7308

Application/License No. WH03022

G1 THERAPEUTICS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 700 Park Offices Drive, Suite 200 Research Triangle Park, NC 27709 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 18, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of October, 2024.

APPLICANT/PRINCIPAL
G1 THERAPEUTICS, INC.

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Diana Wilson

Witness Rebecca Medina

Countersigned by:

Nevada Resident Agent Christopher P. Troha

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Derek J. Elston, Jennifer L. Jakaitis, Richard Casas, Rachel Fore, Aaron D. Griffin, Bartlomiej Siepierski, Christopher P. Troha, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Marluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of 30th day of October, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2021

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler G1 Therapeutics, Inc.

Pharmacy/Wholesaler License # (if applicable) WH03022

Physical Address 700 Park Offices Drive, Suite 200

City Research Triangle Park State NC Zip 27709

Mailing Address (if different from physical address) 700 Park Offices Drive, Suite 200, P. O. Box 110341

City Research Triangle Park State NC Zip 27709

Telephone 919-213-9835 Website https://www.g1therapeutics.com/

Licensing Company Email licensing@g1therapeutics.com

Section 2: Personal Information

First Jonathan Middle Paul Last Lindberg

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 700 Park Offices Drive, Suite 200

City Research Triangle Park State NC Zip 27709

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Elon University		/ - /	
Address	**City**	**State**	**Zip**
Elon	100 Campus Dr.	NC	27244
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
Elon University		/ - /	
Address	**City**	**State**	**Zip**
100 Campus Dr.	Elon	NC	27244
Diploma/Degree obtained, if any			
BS Accounting			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/12 - Present	[redacted]	[redacted]	NC	27615
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
G1 Therapeutics, Inc			08/22 - Present
Business Address	**City**	**State**	**Zip**
P.O. Box 110341, 700 Park Offices Drive, Suite 200	Research Triangle Park	NC	27709
Phone	**Title**	**Number of Employed Hours**	
919-213-9835	Sr. Director, Development Operations	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Propella Therapeutics, Inc.			09/20 - 08/22
Business Address	**City**	**State**	**Zip**
120 Mosaic Blvd	Pittsboro	NC	27312
Phone	**Title**	**Number of Employed Hours**	
(855) 244-4546	Sr. Director, Operations	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
BioDelivery Sciences International, Inc.			04/12 - 09/20
Business Address	**City**	**State**	**Zip**
	Raleigh	NC	
Phone	**Title**	**Number of Employed Hours**	
	Director, Corporate Operations	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
PRA Health Sciences, Inc.			09/09 - 02/12
Business Address	**City**	**State**	**Zip**
	Raleigh	NC	
Phone	**Title**	**Number of Employed Hours**	
	Strategic Account Manager Proposal Analyst	40/week	
Description of Duties			
See attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Jonathan P. Lindberg, [redacted]

QUALIFICATION SUMMARY

Life sciences clinical operations leader with over 20 years of project and finance management experience, including nearly 15 years focused on oncology and CNS research. Recognized by peers as a savvy and adept negotiator with the ability to positively impact the performance of large, diverse teams. Effective planner and communicator with a demonstrated track record of achieving efficient project outcomes while consistently meeting both budgetary and timeline objectives.

EDUCATION

MBA – Elon University
BS, Accounting – Elon University
BS, Management – Elon University

PROFESSIONAL EXPERIENCE

G1 Therapeutics, Inc., RTP, NC

Sr. Director, Development Operations
March 2024 – Present

- Responsible for line management of four functional areas: Technical Operations (CMC), Clinical Operations, Data Management, and Project Management.
- Oversee Project Management on all programs and provide insight and understanding relative to current and future planning needs.
- Assign and provide oversight of clinical study teams, data management and clinical supply staff, including management of vendors (e.g., CRO) and coordination of associated activities.
- Oversee Technical Operations (CMC)
- Ensure proactive analysis and reporting on all programs in collaboration with cross-functional project teams.
- Develop budgets for functional areas, manage and allocate resources and monitor expenditures.
- Provide leadership and day-to-day management of staff members including development, motivating, coaching.
- Participate in and/or lead company/department/team meetings and projects as required.
- Ensure that clinical trial projects are properly resourced, managed and executed within scope/budget and in accordance with established timelines and quality standards.
- Attend project team meetings as needed and provide study updates to senior management
- Assist in identification and management of third-party vendors, including development of Request for Proposals (RFPs), scope of work (SOW) documents, and vendor specifications.
- Provide cadenced updates to other departments to ensure communication and good relationships in connection with matters related to clinical trial projects.
- Coordinate with Quality Management on all activities related to audit findings and/or identification of significant site non-compliance.
- Participate in, as assigned, Joint Operating Committees and/or Executive Steering Committees with key partners and governance meetings with key vendors.

Senior Director, Project Management
August 2022 – March 2024

- Oversee Project Management function, responsible for planning, leading, and delivering upon key strategic corporate objectives on time and within budgetary parameters
- Participate in Senior Leadership Team initiatives to support efficient deployment of company resources

- Contribute toward the Therapeutic Strategy Leadership Team (TSLT) objectives of driving key decision-making activities forward for the Trilaciclib (Cosela) clinical development pipeline
- Create, modify, maintain, and improve upon operational processes
- Liaise with cross-functional teams across all disciplines to ensure timely, accurate, and transparent communication of ongoing company activities

Propella Therapeutics, Inc., Pittsboro, NC

Sr. Director, Operations
September 2020 – August 2022

- Hold primary timeline and budgetary planning responsibility for a pipeline of clinical development programs within a privately held, Oncology-focused biotech
- Develop and maintain company R&D budget with annual spend of ~$10M
- Forecast timing for all program costs, negotiate & manage all vendors agreements
- Liaise with cross-functional teams across all disciplines to create cohesive CDPs
- Organize and chair internal development planning meetings

BioDelivery Sciences International, Inc. (BDSI)

Director, Corporate Operations
Director, Corporate Strategy
Associate Director, Ops & Finance
Senior Manager, Ops & Finance
Manager, Contracts & Project Mgmt.
April 2012 – September 2020

- Contributed and helped lead 2 separate clinical development programs that resulted in NDA approvals
- Managed CROs & vendors for an R&D pipeline with total spend >$120M
- Developed the 3-year Operating Budget for a spec pharma firm with over $100M in annual Net Revenue
- Represented BDSI in an industry Consortium as program finance lead, resulting in savings to group of over $2M in first year
- Served as finance lead on a joint development committee in partnership with a mid-size pharma company
- Managed all vendors for an R&D pipeline with total spend > $100M
- Negotiated over $34 Million in total discounts, rebates, and savings from vendors
- Primary Alliance Lead in partnership with a large Pharma company
- Managed procurement efforts for international manufacturing supply chain
- Provided CDMO oversight and management, focusing on COGS reduction efforts which yielded reductions of > 60% per unit
- Generated an Enterprise Strategy Plan to support rapid growth and expansion
- Created structure and formalized processes across multiple Operational areas including Procurement, Finance, Manufacturing, Facilities, and IT
- Led organizational communication for Executive Leadership Team and BOD
- Implemented a new communications platform and developed BOD materials
- Participated in Business Development initiatives, helping to evaluate potential acquisitions and both in and out-licensing opportunities on global basis

PRA Health Sciences, Inc., Raleigh, NC ***Strategic Account Manager, Proposal Analyst, September 2009 – February 2012***

- Collaborated with members of ClinOps, Finance, BD, and Legal Services to generate and execute over 100 Phase II-IV agreements
- Developed over 200 Proposals/Change Orders totaling $500M+ in total value
- Standardized processes for efficient development of contracts to support high volume through-put, executing 62 new award Agreements in a calendar year
- Reduced internal contract development cycle time by 50%
- Maintained relationships with sponsor stakeholders on a Top 5 client account
- Customized a proprietary pricing tool for a strategic FSP partnership

Toll Brothers Inc., Leesburg, VA & Martinsburg, WV ***Project Manager, Assistant Project Manager, June 2004 – September 2007***

- Managed Team of 8-10 professionals across a variety of functions
- Established and monitored master project schedule, managed regular progress meetings with team, assigned resources and prioritization to critical path tasks
- Continuously monitored project costs against budgets for ongoing single-family home developments, with typical results within +/- 0.5% of budget
- Negotiated and maintained contracts for over 75 vendors
- Compiled data and project review / market analyses on quarterly basis for presentation to company executives and regional management
- Trained project teams of 8-12 on operating procedures including change order preparation, submission, issuance, and acceptance procedures
- Monitored all vendor expenses and shouldered primary oversight responsibilities for P&L of multi-million-dollar residential projects
- Completed extensive weekly and monthly reporting to regional and corporate offices pertaining to all facets of operations

PUBLICATIONS / PRESENTATIONS

- Outsourcing In Clinical Trials Southeast (OCT-SE) – Speaker's Panel (2016)
- Clinical Trial Supply Southeast (CTS-SE) – article published (2015)

ASSOCIATIONS / CERTIFICATIONS / AWARDS

- Project Management Institute (PMI)
- North Carolina Project Management Institute (NCPMI)

PROFESSIONAL DEVELOPMENT AND TRAINING

- Project Management Professional (PMP) Certification, #506732
- Elon Executive Education – Project Management Certificate (2008)

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Jonathan Lindberg, **certify that as the designated representative for**

G1 Therapeutics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Lindberg

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

October 9, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lindberg

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

October 9, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Durham

I, Jonathan Lindberg, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

October 9, 2024

Date

Subscribed and Sworn to before me this 9th day of October, 2025.

Notary Public Signature

Kimberly Whetstone

my commision expires: 02/16/2026

KIMBERLY WHETSTONE
NOTARY PUBLIC
My Commission Expires February 16, 2026
WAKE COUNTY, NC
(Seal)

G1 Therapeutics Inc - Employee List

First name	Last name	ffice Location
Corinne	Mounier	Company HQ
Kelly	McCarter	Company HQ
Vicky	Hicks	Company HQ
Sandra	James	Company HQ
Kim	Whetstone	Company HQ
Kyle	Davis	Company HQ
Maggie	Gagnon	Company HQ
Michael	Townsend	Company HQ
Julio	Ruiz	Company HQ
Daniel	Barnes	Company HQ
David	Mangum	Company HQ
Shannon	Lusk	Company HQ
Whitney	Page	Company HQ
Elisabeth	Henderson	Company HQ
Ryan	Stewart	Company HQ
Jonathan	Lindberg	Company HQ
Jawahar	Ruddarraju	Company HQ
Billy	Hill	Company HQ

4H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Nuvation Bio Inc.

Physical Address: 10 Burlington Mall Road, Suite 250

City: Burlington State: MA Zip: 01803

Mailing Address (if different from physical address): 1500 Broadway, Ste 1401

City: New York State: NY Zip: 10036

Telephone: (332) 208-6102 Website: Nuvation Bio Inc.

Name of Designated Representative (DR): Kerry Wentworth

Licensing Company Email: licensing@nuvationbio.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies, Specialty Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within the last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): N/A

Corporation Name: Nuvation Bio Inc.

Mailing Address: 1500 Broadway, Ste 1401

City: New York State: NY Zip: 10036

Telephone: (332) 208-6102 Email: licensing@nuvationbio.com

Contact Person Name: Kerry Wentworth

Date of SEC Registration:	SEC Registration Number: 333-254176	Stock Exchange Symbol: NUVB

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

31 Oct 2024
Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nuvation Bio Inc.
Facility Name

Kerry Wentworth
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

31 Oct. 2024
Date

Board Use Only	Date Received: 11/18/24	Amount: $1000 - ck 2673

Senneth Greene

From: [redacted]
Subject: FW: Labeler Code Assigned: 84651

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, August 9, 2024 11:24 AM
To: Kerry Wentworth <[redacted]
Subject: [EXT] - Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 09-AUG-2024
Labeler DUNS: 119311388
Labeler Name: Nuvation Bio Inc.
Labeler Code Assigned: 84651

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.



Company/Ownership Information

Nuvation Bio, Inc.
10 Burlington Mall Road
Suite 250
Burlington MA 01803
(332) 208-6102
licensing@nuvationbio.com

Tax ID: 85-0862255
Nuvation Bio is publicly traded on the NYSE (Symbol: NUVB)

Company Officers

Moses Makunje, VP Finance

Colleen Sjogren, Chief Commercial Officer

Kerry Wentworth, Chief Regulatory Officer

Nuvation Bio

Description of Operations

Nuvation Bio, Inc. is a VirtualManufacturer. Nuvation Bio, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors and Specialty Pharmacies by their Third-Party Logistics Provider, Cardinal Health , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturers to produce our product:

Asymchem Life Science (Tianjin) Co., Ltd.
7th Avenue, TEDA Tianjin, Tianjin, 300457, China (CHN)
FDA Establishment Number: 3007060980

Cardinal Health Packaging Solutions ("CHPS")
339 Mason Road
LaVergne, TN 37086

Asymchem manufactures Nuvation Bio, Inc.'s product and CHPS packages finished product. At no time does Asymchemor CHPS own the product, contract with Nuvation Bio, Inc.'s customers, invoice, nor sell a Nuvation Bio, Inc. product. Nuvation Bio, Inc.'s products are not Controlled Substances.

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health acts as Nuvation Bio, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Nuvation Bio, Inc.'s product throughout the United States. Cardinal Health's address is:

ICS
167 International Blvd
Brooks, KY 40109

Additional Information:

- Nuvation has 150 total employees `10 employees working on site during normal business hours
- Nuvation Bio, Inc.'s hours of operation are 10:00 am – 4:00pm Monday through Friday
- Nuvation Bio, Inc.'s records are stored at 1500 Broadway, Suite 1401, New York, NY 10036
- Nuvation Bio, Inc.'s facility square footage is 2235

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NUVATION BIO INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NUVATION BIO INC." WAS INCORPORATED ON THE TWENTY-FOURTH DAY OF APRIL, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7946403 8300

SR# 20243848064

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204537859

Date: 10-02-24

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Nuvation Bio Inc.
10 Burlington Mall Road, Suite 250
Burlington, MA 01803

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200103

Type: Virtual Manufacturer

Issue Date: 08/05/2024

Expiration Date: 08/05/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

Tel: 617-624-6000
www.mass.gov/dph

MAURA T. HEALEY
Governor
KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary
ROBERT GOLDSTEIN, MD, PhD
Commissioner

Verification of Licensure

11/12/2024

To Whom It May Concern:

The organization named below has received the following in the Commonwealth of Massachusetts:

Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration

Name of Organization: Nuvation Bio Inc.

Registration Number: VIR200103
Registration Status: Current
Issue Date: 08/05/2024
Expiration Date: 08/05/2025
Disciplinary Actions: There are no disciplinary actions against this registration.

Registration verification may be obtained at http://checkahealthlicense.mass.gov/. The information provided in this "Verification" is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the "Verification." Disciplinary status is defined as voluntary surrender, revocation, suspension or probation of a license. The "Verification" does not include information about the existence, absence, or status of complaints. To request such information, please submit a public record request to publicrecordsadmin@massmail.state.ma.us.

Traci Westgate

Traci Westgate
Director

Nuvation Bio

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

Re: Nuvation Bio, Inc - Employee List

Below please find the employee list of those individuals involved in the support and administration of Nuvation Bio, Inc. manufacturing and distribution strategy and activities:

Tom Boeing - SVP, Market Access & Commercial Strategy

David Abbott- Executive Director, Payer, Trade, & Distribution

Edward Kawamura – Sr. Director, Trade and Distribution

Qi Jin - Sr Director, Drug Product

Ken Fogle - Sr Dir, Head of Supply Chain

An official website of the Commonwealth of Massachusetts Here's how you know

— Menu

Mass.gov Search Mass.gov SEARCH

(/) > Professional Licenses & Permits (/topics/professional-licenses-permits) > ... > Additional PMP Information (/additional-pmp-information) > MCSR for I

Policies and guidelines for MCSR

See the policies and guidelines for the Massachusetts Controlled Substances Registration (MCSR).

Notices & Alerts

Transitioning to a new online licensing system | *Updated Jan. 5, 2024, 09:30 am*

Beginning on January 29, 2024, Dentistry MCSR and Physician MCSR licenses issued by Massachusetts Controlled Substance Registration system will transition to an online licensing system. Learn more... (/news/transitions-to-a-new-online-licensing-system)

Issuance of MCSR to health facilities

Regulations of the Department of Public Health at 105 CMR 700.003 permit the issuance of a Massachusetts Controlled Substances Registration (MSCR) to licensed health facilities as defined in 105 CMR 700.001. A health facility includes the following:

- A hospital, hospital pharmacy, long-term care facility or clinic licensed or maintained by the Department
- A public medical institution as defined in M.G.L. c. 118E § 8
- Any institution licensed or maintained by the Department of Mental Health
- Any hospital, long-term care facility or clinic maintained by the Commonwealth
- Any ambulance service licensed by the Department to provide Advanced Life Support services

Health facilities with an MCSR are advised that such registrations are not transferable. A new MCSR is required for a change in name, ownership or address. An MCSR is valid for one year and must be kept current.

For further information, please contact the Drug Control Program.

Additional Resources

See Mass General Law Chapter 118 (https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVII/Chapter118)

Requirements for individuals with limited medical licenses

Regulations of the Department of Public Health at 105 CMR 700.004 (B)(5) permit residents and clinical fellows who have limited medical licenses and wish to prescribe, dispense and administer controlled substances to utilize the registration of the hospital in which he/she is employed provided the following criteria are met:

- A person must be authorized to dispense controlled substances under M.G.L. c. 112, if applicable
- Such dispensing must be done in the usual course of business or professional practice
- The hospital by whom a person is employed must verify with the Board of Registration in Medicine that the individual is permitted to dispense controlled substances
- The person must only act within the scope of his/her employment at the hospital
- The hospital must authorize the person to dispense controlled substances under the registration number of the hospital and designate a specific suffix number to the hospital's registration number preceded by a hyphen for each person authorized
- The hospital must maintain a current list of internal codes and make these codes available at all times to other registrants, the Commissioner and authorized law enforcement agencies

It should be noted that individual hospitals determine whether or not they wish to permit persons with limited licenses to use the registration of the hospital. Should a hospital determine that they do not want individuals with limited licenses to utilize the hospital's registration, the physician must apply to the Department and, where applicable, the U.S. Drug Enforcement Administration (DEA), and receive Controlled Substances Registrations for the period of time for which their limited license is issued. Upon full licensure by the Board of Registration in Medicine, a physician must then reapply to the Department, and, where applicable, to the DEA for a new full registration(s). The appropriate fee must accompany the application to the Department. The newly issued registration will not be restricted to the period of time in which the limited license was valid.

Additional Resources

See Mass General Law Chapter 112 (https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112)

Address for Individual Practitioner Massachusetts Controlled Substance Registration (MCSR) Applications and Renewals

This Circular Letter is issued by the Drug Control Program (DCP), which is part of the Bureau of Health Professions Licensure (BHPL), regarding the address to be provided in Massachusetts Controlled Substance Registration (MCSR) applications and renewals for practitioners listed in 105 CMR 700.004(A)(2).

A practitioner must have an MCSR for each location where they are responsible for the purchase and/or storage of controlled substances. The address provided for the application must be that of the location. For example, if a practitioner MCSR is used to purchase controlled substances and authorize storage at two separate practice offices, that practitioner must have two separate MCSRs, one for each such practice office. Each of the MCSR applications must list the physical address of the practice office to be covered by the MCSR.

If a practitioner is not responsible for the purchase and/or storage of controlled substances, they may use any address where DCP can direct program communications for the practitioner. For example, if a Practitioner only prescribes and administers controlled substances, they may use any address where the practitioner can be regularly reached, including the following:

- A post office box or other mail collection type location is permissible for this category of MCSR. The practitioner will be responsible for the prompt receipt and response to communications sent to such an address.
- A practitioner may also elect to use a home address, noting that all MCSR related addresses are considered public information, and will be provided in response to public records requests, unless the practitioner qualifies for a Public Records Law exemption and requests suppression of this personal information.
  Request health profession license information confidentiality benefits | Mass.gov (/how-to/request-health-profession-license-information-confidentiality-benefits)

Please direct any questions or concerns to The Drug Control Program at dcp.dph@mass.gov (mailto:dcp.dph@mass.gov).

Additional Resources

Circular Letter: DCP 23-04-116 (https://www.mass.gov/news/circular-letter-dcp-23-04-116)

Massachusetts Controlled Substance Registrations (MCSRs) for Third Party Logistics Providers, Virtual Manufacturers and Virtual Distributors

This Circular Letter is issued by the Drug Control Program (DCP), which is part of the Bureau of Health Professions Licensure, regarding registration of Third Party Logistics Providers (3PLs), Virtual Manufacturers and Virtual Distributors. The purpose is to assist registrants who conduct these kinds of operations to understand which of the three MCSRs available for virtual activities best meets the needs of their business.

1. ***Selecting the Appropriate MCSR Category***

A **Virtual Manufacturer** is a person/entity with a principal place of business in the Commonwealth of Massachusetts but which never takes physical possession of controlled substances in the Commonwealth. [1] (/news/circular-letter-dcp-23-04-117#_ftn1) An example of a Virtual Manufacturer could be a person/entity with a principal office in Massachusetts, while its manufacturing operations are located in another state. Manufacturing operations are managed or directed in Massachusetts, but no controlled substances are manufactured or stored in Massachusetts. An MCSR for virtual manufacturing would also authorize the person/entity to conduct virtual distribution of its own controlled substance products.

A **Virtual Distributor** is a person/entity with a principal place of business in Massachusetts but which never take physical possession of controlled substances in Massachusetts.[2] (/news/circular-letter-dcp-23-04-117#_ftn2) An example of a Virtual Distributor could be a person/entity with a principal office in Massachusetts, while its distribution centers, warehouses, trucking operations, etc. are all located in other states. Distribution operations are managed or directed in the Massachusetts, but no controlled substances are received or stored in Massachusetts.

A **3PL** is an entity that provides or coordinates warehousing, or other logistics services, of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. 3PLs are federally regulated under 21 U.S.C. § 360eee-3. A 3PL may choose to conduct purely virtual activities in Massachusetts , where it directs or manages from Massachusetts but does not receive or store controlled substance here. However, under current federal law, a 3PL may also employ a business model where it takes custody of controlled substances as part of the logistical arrangements being made. An example of this might be that a 3PL chooses to store controlled substances in its warehouse or distribution center located in Massachusetts as part of its operations.

The primary difference between Virtual Manufacturers/Distributors and 3PLs is that Virtual Manufacturers and Distributors never take possession of any controlled substance in Massachusetts, while a 3PL may choose to do so.

2. ***Pre-Registration Inspections***

Virtual Manufacturers and Distributors register with the Commonwealth of Massachusetts primarily because regulators in other states require that they be registered in their "home" state to conduct operations in the other state. For these registrants, no physical inspection of their premises in Massachusetts will be conducted, unless requested. If, at any point, a Virtual Manufacturer or Distributor plans to have controlled substances on site, it must register with DCP for an appropriate MCSR (e.g. manufacturer or distributor) and complete an inspection.

Federal law requires that a 3PL be registered with any state where the 3PL distributes a controlled substance to or from such state.[3] (/news/circular-letter-dcp-23-04-117#_ftn3) Federal law also bars states from licensing/registering 3PLs as wholesale distributors.[4] (/news/circular-letter-dcp-23-04-117#_ftn4) Therefore, the Drug Control Program is making a 3PL MCSR available for this kind of business. To register, a 3PL will need to certify on its initial application and any subsequent renewal applications whether it will be taking custody of controlled substances in Massachusetts. If it is taking custody in Massachusetts, an inspection will be conducted of the necessary premises. If it is registering here for purely virtual activities, no inspection will be conducted, unless requested.

Please direct any questions or concerns to the Drug Control Program: **dcp.dph@mass.gov** (mailto:dcp.dph@mass.gov).

[1] (/news/circular-letter-dcp-23-04-117#_ftnref1) M.G.L. c. 94C, §7(i); 105 CMR 700.001 (Definitions).

[2] (/news/circular-letter-dcp-23-04-117#_ftnref2) M.G.L. c. 94C, §7(i); 105 CMR 700.001 (Definitions).

[3] (/news/circular-letter-dcp-23-04-117#_ftnref3) 21 U.S.C. § 360eee-3(a).

[4] (/news/circular-letter-dcp-23-04-117#_ftnref4) 21 U.S. Code § 360eee–4(b)(2).

Additional Resources

Circular Letter: DCP 23-04-117 (https://www.mass.gov/news/circular-letter-dcp-23-04-117)

Contact

Massachusetts Controlled Substances Registration

Online

MCSR@Massmail.State.MA.US (mailto:MCSR@Massmail.State.MA.US)

Phone

(617) 973-0949 (tel:6179730949)

Fax

(617) 753-8233

Address

250 Washington Street, 3rd Floor, Boston, MA 02108

Directions (https://maps.google.com/?q=250+Washington+Street%2C+3rd+Floor%2C+Boston%2C+MA+02108)

RELATED

105 CMR 700.00: Implementation of MGL c.94C (/regulations/105-CMR-70000-implementation-of-mgl-c94c)



(/)

All Topics (/topics/massachusetts-topics)

Site Policies (/massgov-site-policies)

Public Records Requests (/topics/public-records-requests)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-39351

NUVATION BIO INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-0862255**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1500 Broadway, Suite 1401 New York, New York	**10036**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (332) 208-6102

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, Par Value $0.0001 Per Share	**NUVB**	**New York Stock Exchange**
Warrants to Purchase Class A Common Stock	**NUVB.WS**	**New York Stock Exchange**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting common stock, par value $0.0001 per share, held by non-affiliates of the registrant computed by reference to the closing sales price for the registrant's common stock on June 30, 2023, as reported on the New York Stock Exchange was approximately $261,249,647.

In determining the market value of the voting stock held by any non-affiliates, shares of common stock of the registrant beneficially owned by directors and officers have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 16, 2024, the registrant had 218,046,219 shares of Class A common stock and 1,000,000 shares of Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant's definitive proxy statement relating to the Company's Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2023, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "plan," "should," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described herein under "Item 1A—Risk Factors." You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Annual Report on Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or the SEC, after the date of this Annual Report on Form 10-K.

SUMMARY RISK FACTORS

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the section titled "*Risk Factors*" in Item 1A of this Annual Report on Form 10-K. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described in the section titled "*Risk Factors*" as part of your evaluation of an investment in our securities:

- We have a limited operating history and have incurred significant losses since inception and anticipate that we may continue to incur losses for the foreseeable future, and may never achieve or maintain profitability.
- We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts. Additionally, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- If we do not obtain regulatory approval for and successfully commercialize our product candidates in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable.
- Our approach to the discovery and development of product candidates based on our Drug-Drug Conjugate platform is unproven and is based on novel technology, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.
- Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.
- We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

- If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.
- We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight.
- We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of NUV-868 and our other current and future product candidates.
- If we are not able to establish collaborations, we may have to alter some of our future development and commercialization plans.
- Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations including equivalent foreign laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), shippers and others.
- Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

- The dual-class structure of our common stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control.

PART I

Item 1. Business.

Business Combination of Panacea Acquisition Corp. and Nuvation Bio Inc.

On February 10, 2021, (the "Closing Date"), Nuvation Bio Inc., a Delaware corporation ("Legacy Nuvation Bio"), Panacea Acquisition Corp. ("Panacea"), and Panacea Merger Subsidiary Corp, a Delaware corporation and a direct, wholly owned subsidiary of Panacea ("Merger Sub") consummated the transactions contemplated by an Agreement and Plan of Merger among them dated October 20, 2020 ("Merger Agreement").

Pursuant to the terms of the Merger Agreement, a business combination of Panacea and Legacy Nuvation Bio was effected through the merger of Merger Sub with and into Legacy Nuvation Bio, with Legacy Nuvation Bio surviving as a wholly owned subsidiary of Panacea (the "Merger"). On the Closing Date, Legacy Nuvation Bio changed its name to Nuvation Bio Operating Company Inc. and Panacea changed its name to Nuvation Bio Inc. (the "Company" or "Nuvation Bio").

In connection with the closing of the Merger, our Class A common stock and warrants to purchase shares of our Class A common stock began trading on The New York Stock Exchange under the symbols "NUVB" and "NUVB.WS," respectively, on February 11, 2021. The disclosure in Items 1 and 1A of this report gives effect to the Merger and includes the operations of Legacy Nuvation Bio prior to the Merger.

Business Overview

We are a clinical-stage biopharmaceutical company tackling some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates. We were founded in 2018 by our chief executive officer, David Hung, M.D., who founded Medivation, Inc. and led its successful development of oncology drugs Xtandi® and talazoparib (now marketed as Talzenna®), leading to its $14.3 billion sale to Pfizer Inc. ("Pfizer") in 2016.

We leverage our team's extensive expertise in medicinal chemistry, preclinical discovery, manufacturing, drug development and commercialization to bring forward novel small molecules that improve the activity and overcome the liabilities of currently marketed drugs to address major unmet needs in oncology.

The foundations of our approach include:

- ***The pursuit of validated targets***: We identify and pursue oncology targets validated by strong clinical or preclinical data that provide a high degree of confidence in generating clinically meaningful benefit. We focus on targets where there has been some progress by others in generating clinical candidates or FDA-approved drugs, and we then attempt to design novel therapeutic candidates to overcome the encountered safety liabilities or limitations in efficacy.
- ***Innovative medicinal chemistry expertise:*** We use our medicinal chemistry proficiency to generate differentiated therapeutic candidates, focused on improving their safety, anti-tumor activity and pharmacologic profiles over other standard of care ("SOC") therapies. We also use innovative medicinal chemistry approaches to generate novel classes of molecules such as our DDCs.
- ***Human capital management***: We believe our employees are our greatest assets, and we recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. We are building a culture that fosters a productive, professional and inclusive work environment, where our employees can thrive, have fun, and be inspired to perform their best work.

The following table summarizes our product candidate pipeline:



Our most advanced clinical stage product candidate, NUV-868, is a BD2-selective oral small molecule BET inhibitor. NUV-868 inhibits the protein BRD4, a key member of the BET family that epigenetically regulates a number of important proteins that control tumor growth and differentiation, including oncogenes such as c-myc. Notably, BET proteins have critical biological functions and are found to be altered in many human cancers (Bechter and Schoffski, 2020). We have designed NUV-868 to potentially reduce the therapeutic limiting toxicities of BRD4 inhibitors currently in development by optimizing BD2 versus BD1 selectivity. NUV-868 is almost 1,500 times more selective for BD2 than BD1. Non-selective BD1/2-inhibitors in development have been associated with tolerability issues, potentially due to BD1 inhibition, especially in the gastrointestinal ("GI") tract and bone marrow (Faivre et al 2020). NUV-868 in combination with PARP inhibitors may have synergistic activity to increase efficacy across multiple solid tumors. In addition, NUV-868 in combination with androgen receptor-directed therapies may help to overcome resistance in prostate cancer. In January 2022, the FDA cleared an IND application for NUV-868 for the treatment of patients with advanced solid tumors and we initiated a Phase 1 monotherapy dose escalation study for this indication in March 2022 to determine a maximum tolerated dose ("MTD"). In December 2022, we initiated a Phase 1b dose escalation study of NUV-868 in combination with olaparib in patients with ovarian cancer, pancreatic cancer, metastatic castration-resistant prostate cancer ("mCRPC"), triple negative breast cancer ("TNBC"), and other solid tumors, and in combination with enzalutamide in patients with mCRPC. We have completed the Phase 1 monotherapy study and determined the maximum tolerated dose. The combination studies are ongoing.

Our DDC platform is a novel therapeutic approach within the drug-conjugate class of anti-cancer therapies with parallels to Antibody-Drug Conjugates ("ADCs"). ADCs have been effective treatments in oncology, with at least eleven drugs approved by the FDA and an estimated $11.0 billion in worldwide sales expected in 2023. We believe our DDC candidates could expand the therapeutic potential for the drug-conjugate class due to inherently differentiated properties versus ADCs, including a potentially simpler manufacturing process, the potential to cross the cell membrane and recognize intracellular targets, and the potential for oral or intravenous ("IV") dosing. We are designing DDCs to selectively deliver potent anti-cancer therapeutics to cancer cells to exert greater toxicity against these target tumor cells than against healthy non-target tissues. Utilizing this platform, we are able to conjugate tissue-selective targeted small molecules with anti-tumor agents to create unique therapeutic candidates. We have demonstrated this by synthetically fusing a proven anti-cancer small molecule drug to a second small molecule that selectively binds distinct receptors that are preferentially expressed in cancer cells. These tissue-specific receptors create a "sink" that not only may concentrate the targeted drug in cancer cells but may also magnify the effects of the drug in those cells, while preventing similar effects in cells that do not express the targeted receptor. We believe this would allow our DDC candidates to limit some of the adverse effects commonly seen with many cancer drugs, such as bone marrow suppression and GI toxicity. Because this program at its core fuses the active sites of two or more small molecules to each other to generate a new small molecule with improved activity and targeted specificity, they are called DDCs. In January 2024, we announced that the FDA cleared an IND application for NUV-1511, the first clinical candidate from our DDC platform.

Strategy

We strive to deliver meaningful benefit to patients with serious unmet medical needs in oncology by developing novel and differentiated therapies. The core elements of our strategy include:

- ***Rapidly advance the development of our clinical stage product candidate, NUV-868, a BD2-selective oral small molecule BET inhibitor, toward regulatory approval for the treatment of various cancers.*** We have advanced NUV-868 through preclinical studies that have informed a robust clinical development plan. We plan to explore NUV-868 in combination with SOC or other agents in multiple tumor types. We initiated a Phase 1 monotherapy dose escalation study of NUV-868 in March 2022 and a Phase 1b dose escalation study of NUV-868 in combination with olaparib or enzalutamide in December 2022. We intend to initiate a Phase 2 study to further explore safety and efficacy across multiple tumor types once the recommended Phase 2 dose is determined.
- ***Advance candidates from our DDC platform to expand our oncology-focused pipeline.*** We are developing a pipeline of potent oncology-focused chimeric small molecules which combine tumor-targeting specificity with the anti-cancer activity of known oncology agents. In January 2024, we announced that the FDA cleared an IND for NUV-1511, the first clinical candidate from our DDC platform. In the first half of 2024, we intend on initiating a Phase 1/2 dose study of NUV-1511 that will initially evaluate safety and tolerability, and explore the potential clinical efficacy, in patients with advanced solid tumors who previously received and progressed on or after treatment with Enhertu® and/or Trodelvy® per approved FDA labeling, human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer, mCRPC, pancreatic cancer, and platinum-resistant ovarian cancer ("PROC").
- ***Continue to leverage our deep insights in medicinal chemistry to pursue innovative clinical candidates.*** We have established medicinal chemistry expertise that has enabled us to rapidly pursue our current pipeline and platform. We intend to leverage these capabilities to pursue both new and validated targets in patients with serious unmet medical needs.
- ***Evaluate strategic opportunities to accelerate development timelines and maximize value of our product candidate pipeline.*** We currently own the exclusive worldwide development and commercial rights to each of our product candidates. We intend to evaluate collaborations that could maximize the value of our product candidate pipeline, either through the evaluation of our product candidates in combination with compounds owned by third parties or through geographic collaborations outside of the U.S. that allow us to leverage the existing infrastructure of other companies.
- ***Build a fully integrated global oncology company.*** We intend to continue building a fully integrated research, development and commercialization focused company. Our team's track record of success underscores their proven expertise in discovering, developing and delivering innovative medicines to patients. If our therapeutic candidates are approved, we intend to establish a focused commercial infrastructure and selectively expand our global commercial capabilities.

Programs

Overview of NUV-868: BET Inhibitor Program

NUV-868, a BD2-selective oral small molecule BET inhibitor, inhibits BRD4, a key member of the BET family that epigenetically regulates proteins that control tumor growth and differentiation. BETs consist of two sub-domains: BD1, the inhibition of which is known to contribute to toxicity, and BD2, the inhibition of which is expected to be important for efficacy. BET inhibitors have historically targeted both BD1 and BD2 less selectively, causing gastrointestinal toxicity and bone marrow suppressive effects like thrombocytopenia. NUV-868 is almost 1,500 times more selective for BD2 than BD1 and is designed to alleviate the therapeutic limiting toxicities observed by other non-BD2 selective BET inhibitors. NUV-868 in combination with androgen receptor-directed therapies may help to overcome resistance in prostate cancer. In addition, NUV-868 in combination with PARP inhibitors may have synergistic activity to increase efficacy across multiple solid tumors.

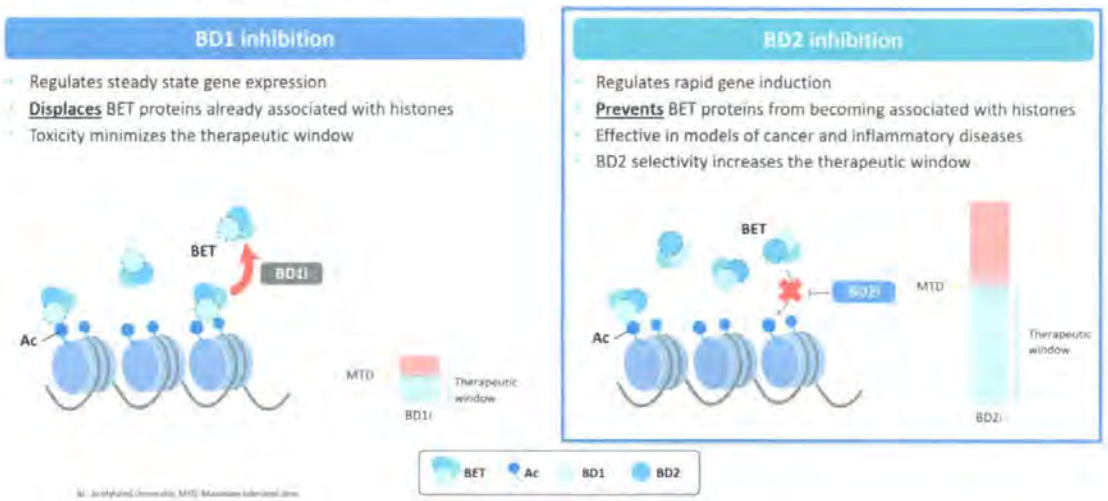
BET Inhibition in Advanced Solid Tumors

The BET family of proteins have critical biological functions and are found to be altered in many human cancers (Bechter and Schoffski, 2020). Genetic screening and nonclinical studies have implicated BET proteins in both hematologic malignancies and in solid tumors. BET proteins have been shown to drive transcription of a variety of oncogenes (reviewed in Taniguchi, 2016). For example, BRD4 was found to be enriched at super-enhancer regions of genes that play a major role in oncogenesis (Loven et al, 2013). Inhibition of BRD4 led to defects in transcription along with decreased mRNA of super-enhancer driven genes, including the Myc oncogene (Loven et al, 2013). Besides genetic alterations, overexpression and perturbation of physiological BET function have been described. Chromosomal translocations involving BRD4 and BRD3 have been identified in particularly aggressive forms of nuclear protein in testis (NUT) carcinomas (NC) (French et al, 2010; French et al, 2008). Overexpression of both BRD2 and BRD4 have been observed in glioblastoma cell lines and stem cells (Pastori et al, 2014). Furthermore, gene amplification and overexpression of BRD4 have been observed in patients with some ovarian cancers (Goundiam et al, 2015). Together, these observations suggest that the BET protein family plays multiple roles in oncogenesis.

BET proteins are epigenetic readers that turn on specific genes by binding unique regions of the genome through their ability to read specific chemical tags on chromatin. In some instances, BET proteins turn on oncogenes that are abnormally expressed in a variety of human cancers, such as c-myc. C-myc is believed to play a role in promoting the growth of up to 70% of all cancers. BET inhibitors have the potential to downregulate the expression of such driver oncogenes. These observations have resulted in the generation and clinical investigation of BET inhibitors in several cancer subtypes.

Emerging evidence suggests distinct roles for the BD1 and BD2 domains of BET proteins (Gilan et al 2020). As described in the figure below, inhibition of BD1 may play a predominant role in regulating steady state gene expression through the displacement of BET proteins already associated with histones. Inhibition of BD1 has also been associated with toxicity (including bone marrow suppression and gastrointestinal effects), which together may limit the therapeutic window for agents which potently inhibit BD1. In contrast, inhibition of the BD2 domain may play a predominant role in regulating rapid gene induction by preventing BET proteins from associating with histones. BD2 selective agents have demonstrated efficacy in both cancer and inflammatory models, while having more limited effects on bone marrow and gastrointestinal cells, and may therefore have a wider therapeutic window than non-BD2 selective BET inhibitors.

BD2 MAY SELECTIVELY BLOCK THE ABILITY OF CANCER CELLS TO INDUCE RESISTANCE PATHWAYS, AND BY AVOIDING BD1 INHIBITION, MAY INCREASE TOLERABILTY



Our Potential Solution –NUV-868

NUV-868 is a small molecule BD2-selective BETi for the treatment of solid tumors that is almost 1,500 times more selective for BD2 than BD1, which may potentially enable this molecule to reduce the toxicities associated with other non-BD2 selective inhibitors. Given BET's potential as an oncology target, there are several BET inhibitors in development for several cancers. Other BET inhibitors that are not as selective for BD2, have been associated with toxicities including bone marrow, gastrointestinal and thrombocytopenia. The selectivity of several BET inhibitors that are currently in development is shown in the table below.

NUV-868 IS A MORE SELECTIVE BD2 INHIBITOR

IC50 values of NUV-868 and other BET inhibitors in development

	BRD4 Affinity[1]		
	BD2 (nM)	BD1 (nM)	Selectivity
NUV-868*	2	2920	1460x
ABBV-744[2]	1.03	340	324x
PLX-2853[3]	Mouse BD1 selectivity		
CPI-0610[1]	17	85	5x
ABBV-075[4]	3	11	3.7x
MK-8628/OTX-015[1]	17	26	1.5x
BI-894999[5]	41	5	0.1x
ZEN-3694[7]	Non-selective		

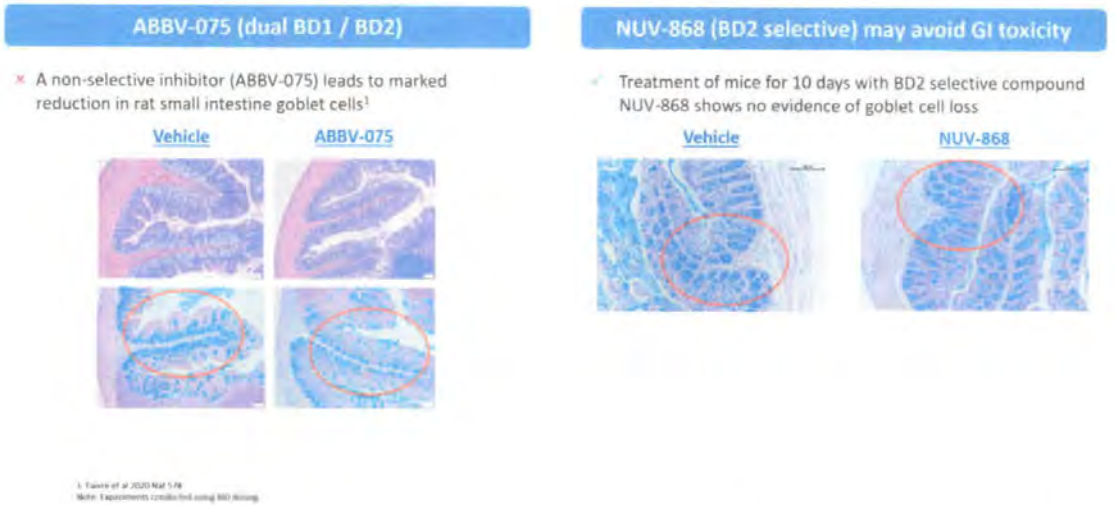
LESS BD2 SELECTIVE → MORE BD2 SELECTIVE

*high plasma protein binding, > 1% free fraction

1. Faivre et al 2020; 2. Various assays used; 3. Internal Nuvation Bio data; 4. https://ash.confex.com/ash/2020/webprogram/Paper140138.html; 5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474678/; 6. https://www.nature.com/articles/s41388-018-0150-2; 7. 2016-EORTCposter-ZenithEpigenetics.pdf

NUV-868's BD2 selectivity may also limit gut toxicity observed with other non-selective BD1/BD2 BET inhibitors. In tissue samples from a rat small intestine treated with vehicle and non-selective BET inhibitor, ABBV-075, treatment with ABBV-075 led to a marked reduction in healthy goblet cells, which are central in protecting the mucous membrane in the GI tract (Faivre et al 2020). By comparison, a notably higher dose (30 mg/kg) of NUV-868 showed no apparent evidence of goblet cell loss in mice. These results are shown in the images below. We believe this data supports the potential for NUV-868 to limit the gastrointestinal toxicities that are associated with other BET inhibitors.

NUV-868: REDUCED GUT TOXICITY COMPARED WITH NON-SELECTIVE BET INHIBITORS IN ANIMAL MODELS



The other main toxicity associated with BET inhibitors is thrombocytopenia. While most non-selective BET inhibitors lower platelet levels and cause thrombocytopenia, NUV-868 has demonstrated higher platelet levels as a function of reversing platelet suppression associated with untreated tumor burden and a lack of bone marrow-suppressive side effects in xenograft studies. In the table below, platelet counts are measured in a MV4-11 AML xenograft hematology panel 24 hours post the final dose of NUV-868 on day 21 across three dose levels. As compared to treatment with vehicle, platelet counts are higher for the NUV-868 cohorts across the low (5 mg/kg), medium (10 mg/kg) and high (20 mg/kg) doses. Additionally, as shown in the table below, daily dosing of NUV-868 at 20 mg/kg to either male or female non-tumor bearing rats did not decrease platelet counts.

NUV-868: LESS BONE MARROW TOXICITY IN ANIMAL MODELS

MV4-11 AML xenograft hematology panel

24-hours post final dose on Day 21

Vehicle		10.4	842	0.20	7.45	361
NUV-868	5	9.6	893	0.19	3.98	438
NUV-868	10	10.2	1290	0.15	5.53	463
NUV-868	20	10.2	1460	0.07	5.93	505

Reverses platelet suppression in an AML xenograft model

Rat 14-day repeat dose study

24-hours post final dose on Day 14

Vehicle		Male	6.29	897	1.16	13.0	36.3
NUV-868	20	Male	6.58	1050	1.80	13.6	37.6
Vehicle		Female	6.73	948	0.60	13.5	37.6
NUV-868	20	Female	6.87	967	1.14	13.4	37.7

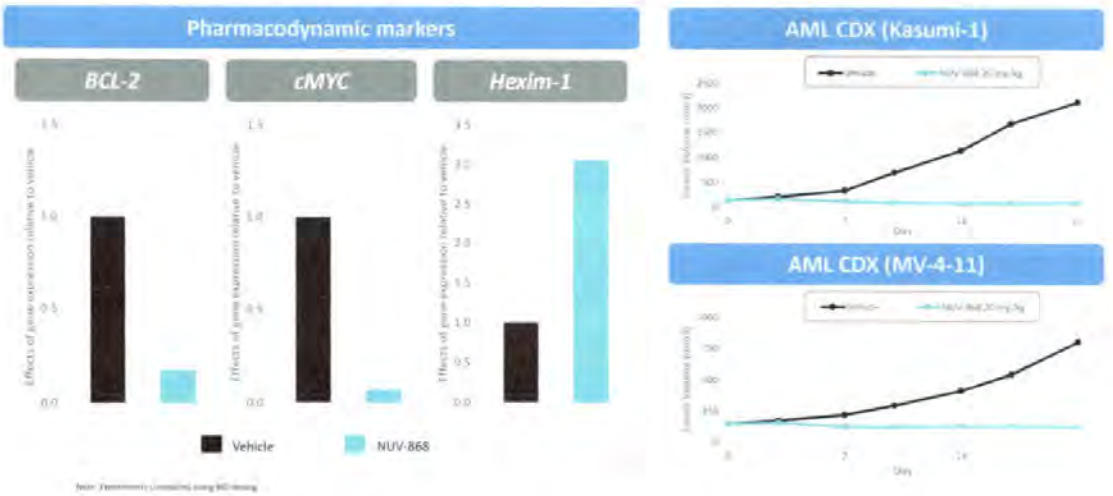
No bone marrow suppression at efficacious doses in rat model

Preclinical Data

In two AML xenograft models, including a Kasumi-1 and an MV-4-11 model, NUV-868 demonstrated anti-tumor activity as compared to vehicle following oral dosing with NUV-868 at 20 mg/kg twice daily (BID) out to 21 days, as shown in the figure below.

The pharmacodynamic effects of NUV-868 were evaluated in a systemic MV-4-11 model. NUV-868 was evaluated at a dose of 20 mg/kg BID. mRNA was isolated from control-treated and NUV-868 treated animals after 5 days of treatment. As demonstrated in the figure below, NUV-868 treatment reduced expression of tumor-promoting genes, c-Myc and BCL-2, and upregulated the tumor suppressor gene, Hexim-1, which is indicative of BET inhibition.

NUV-868 IS HIGHLY POTENT IN KILLING AML CELLS IN IN VIVO XENOGRAFT MODELS; NUV-868 DOWN REGULATES TUMOR PROMOTING ONCOGENES BCL-2 AND MYC AND UP REGULATES TUMOR SUPPRESSOR GENE HEXIM-1



Our Current Opportunities for NUV-868

Overview of Prostate Cancer

Prostate cancer is reported as the second and third leading cause of cancer death for men in the U.S. and in Europe, respectively. SEER cancer statistics estimated that approximately 175,000 men in the U.S. and 450,000 men in the EU5 would be diagnosed with prostate cancer in 2020, potentially resulting in a $15 billion market opportunity given the costs of treatment.

For early-stage prostate cancer, the SOC is a radical prostatectomy, the removal of the prostate via surgery, or radiation therapy. While potentially curative, prostatectomy and/or radiation can result in serious side effects, including urinary and fecal incontinence and erectile dysfunction, as a result of damage to surrounding vital structures, blood vessels and nerves. Given the invasive nature of the procedure, prostatectomy surgery also brings the risk of complications with anesthesia, bleeding, and infection.

mCRPC is the most advanced form of the disease, and there are approximately 35,000 to 45,000 new incidences of mCRPC each year. Men with mCRPC have a poor prognosis and a predicted survival time of less than three years from the initial time of progression.

Current SOC for men with mCRPC provides that patients should initially receive a combination of androgen deprivation therapy ("ADT") and either abiraterone, which works by decreasing androgen levels, or enzalutamide, which works by blocking androgen binding to AR. If the disease progresses despite these second-generation hormonal therapies, chemotherapy is considered the next treatment option. Treatment with chemotherapy is generally postponed for as long as possible due to its effect on patient's quality of life and the potential for severe side effects including

neuropathies, nausea, diarrhea, decreased mental capacity and increased risk of infections.

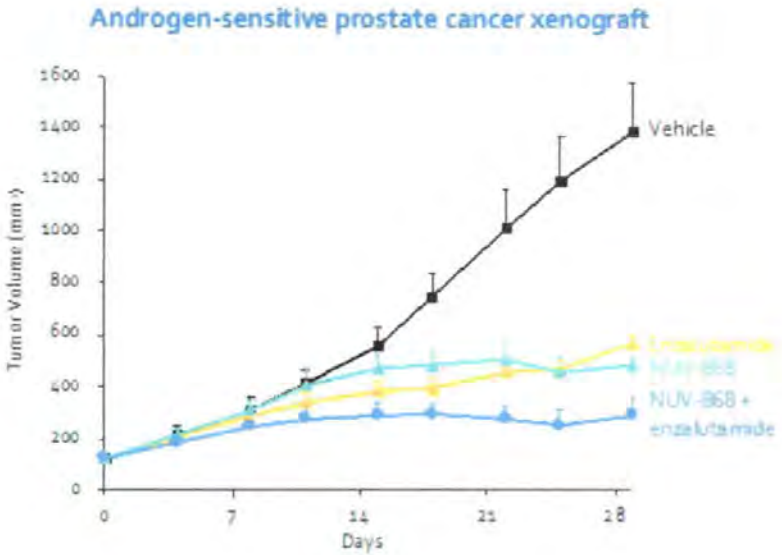
Clinical Rationale for Combining BET Inhibition with Anti-Androgen Therapy in mCRPC

The androgen receptor (AR) plays a pivotal role in castration-resistant prostate cancer, and androgen deprivation therapy is an effective strategy for suppressing the progression of most prostate cancers (Fujita and Nonomura, 2019). Enzalutamide is a nonsteroidal antiandrogen approved for the treatment of castration-resistant and metastatic castration-sensitive prostate cancer. The drug has been studied extensively in the clinic and, along with available real-world data since its approval, shows strong evidence of its efficacy and tolerability (Scott, 2018). Many patients with castration-resistant prostate cancer eventually develop resistance to antiandrogens, including enzalutamide, through a variety of mechanisms related to the AR, including mutation and overexpression (Fujita and Nonomura, 2019). A potential therapeutic strategy to overcome antiandrogen resistance is through BET inhibition, specifically inhibition of BRD4, which has been shown to drive transcription of the AR (Faivre et al, 2017). Data from a nonclinical study showed that a dual AR and BET inhibitor reduced transactivation of the AR mutant that mediates enzalutamide resistance, inhibited proliferation of AR-positive prostate cancer cells, and suppressed growth of prostate cancer xenografts in vivo (Yu et al, 2020). Additional nonclinical data provide evidence that combining BET inhibitors with AR antagonists, such as enzalutamide, could prevent resistance to these antagonists (Asangani et al, 2016). Published results from a Phase 1b/2a study of ZEN-3694 in combination with enzalutamide in patients with mCRPC showed promising preliminary efficacy results (radiographic progression-free survival [rPFS] of 9 months, with a rPFS of 10 months in patients with prior progression on enzalutamide monotherapy) (Aggarwal et al, 2020).

Preclinical Data

The in vivo antitumor activity of NUV-868 alone and in combination with enzalutamide was evaluated in an androgen-sensitive cell line-derived xenograft model, implanted subcutaneously in the flank of immunocompromised mice. NUV-868 was administered orally BID at 20 mg/kg. Treatment with NUV-868 alone, and in combination with enzalutamide, resulted in reduced tumor volume ($p<0.001$) compared to the vehicle-treated group. The combination resulted in significant growth inhibition than enzalutamide ($p<0.01$) or NUV-868 alone ($p<0.05$).

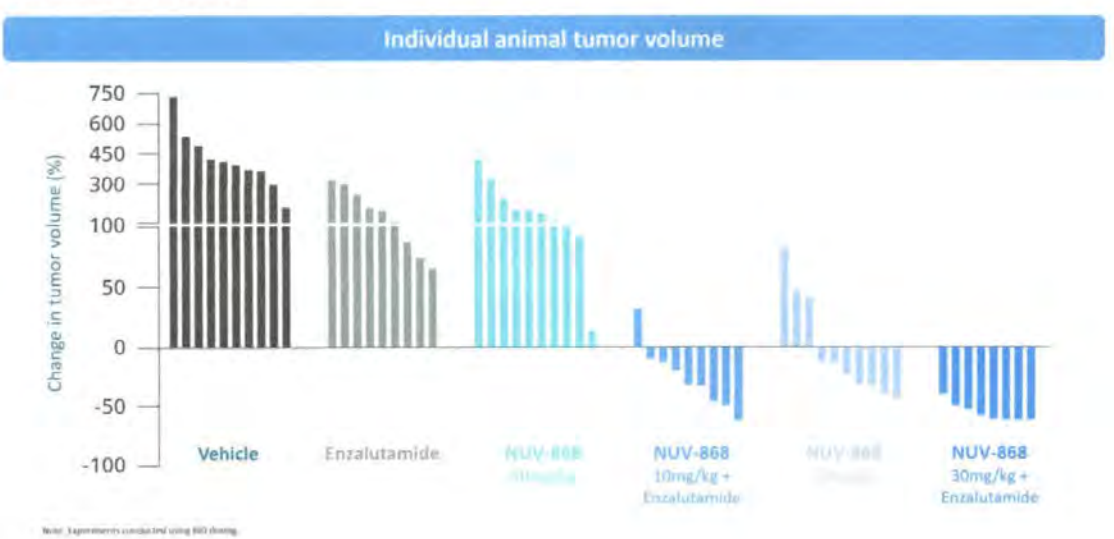
NUV-868 IN COMBINATION WITH ENZALUTAMIDE SIGNIFICANTLY INHIBITS GROWTH OF ANDROGEN-SENSITIVE PROSTATE CANCER XENOGRAFTS



NUV-868 in combination with AR directed therapies may help to overcome resistance in prostate cancer. Inhibition of BRD4 has been shown to drive transcription of the AR (Faivre et al, 2017). BET inhibitors given with AR antagonists, such as enzalutamide, may prevent resistance to these antagonists (Asangani et al, 2016).

NUV-868 as a single agent caused tumor reductions in an enzalutamide-resistant patient-derived prostate cancer xenograft model as noted in the graph below. Additionally, NUV-868 appears to have re-sensitized such tumors back to enzalutamide as the combination caused deep tumor reductions in this model.

NUV-868 TREATMENT CONVERTS ENZALUTAMIDE-RESISTANT PATIENT DERIVED PROSTATE CANCER XENOGRAFTS TO AGAIN BE ENZALUTAMIDE-SENSITIVE



Overview of PARP Inhibitors in various Advanced Solid Cancers

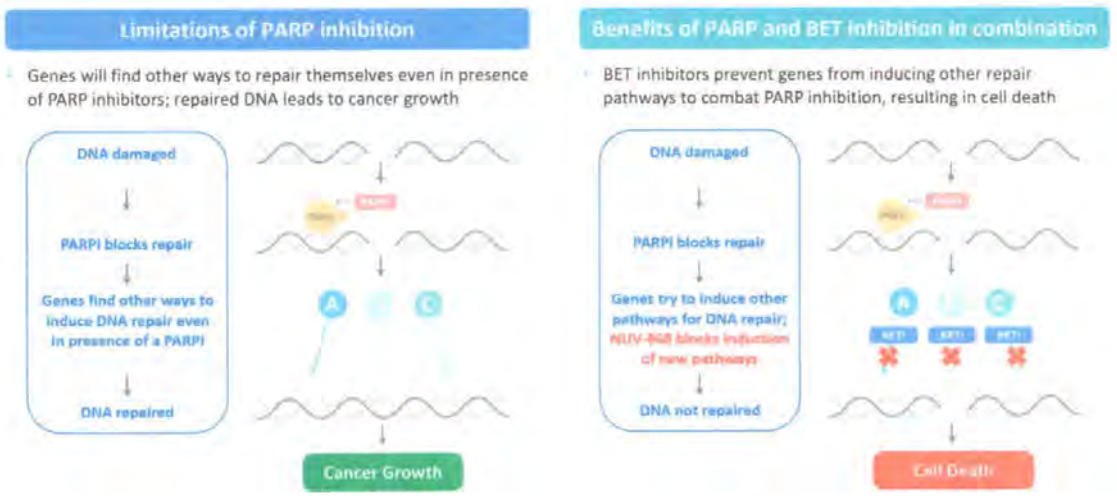
Poly (ADP-ribose) polymerase (PARP) inhibitors block DNA repair and replication in cancer cells. Originally, PARP inhibitors were shown to target cells deficient in breast cancer gene 1 or breast cancer gene 2 (BRCA)-dependent homologous recombination pathways (Farmer et al, 2005); however, nonclinical and clinical evidence suggests that PARP inhibitors may also be effective in cancers lacking BRCA 1/2 mutations through alternative mechanisms (Keung et al, 2020; Kim et al, 2019; Ledermann et al, 2014; Mirza et al, 2016), expanding the potential population who might benefit from PARP inhibition. Several PARP inhibitors have now been approved for solid organ cancers, including ovarian, breast, prostate, and pancreatic cancers; however, their long-term use may be limited due to the development of resistance (reviewed in Kim et al, 2021).

Clinical Rationale for Combining BET Inhibitors with PARP Inhibitors in various Advanced Solid Cancers

Combination therapies that include drugs with other mechanisms of action are being investigated to potentially overcome common mechanisms of resistance to PARP inhibitors. Several nonclinical studies have provided evidence that BET inhibitors in combination with PARP inhibitors may provide synergistic activity against ovarian, breast, prostate, pancreatic, and small cell lung cancers and in cholangiocarcinoma (Fehling et al, 2020; Fiorentino et al, 2020; Karakashev et al, 2017; Liu et al, 2020; Miller et al, 2019; Mio et al, 2019; Pawar et al, 2018; Wilson et al, 2018; Yang et al, 2017). Two clinical studies are currently ongoing to test combination treatment using investigational BET inhibitors alongside approved PARP inhibitors: a Phase 2 study of ZEN-3694 + talazoparib in patients with metastatic or recurrent TNBC (NCT03901469) and a Phase 1/2 study of PLX2853 + olaparib in patients with mCRPC (NCT04556617).

Use of BET inhibitors in combination with PARP inhibitors may also have synergistic activity to increase efficacy across multiple solid tumors, as shown in the figure below. Several nonclinical studies have provided evidence that BETi in combination with PARPi may provide synergistic activity against ovarian, breast, prostate, pancreatic, and small cell lung cancers (Fehling et al, 2020; Fiorentino et al, 2020; Karakashev et al, 2017; Lui et al, 2020; Miller et al, 2019; Mio et al, 2019; Pawar et al, 2018; Wilson et al, 2018; Yang et al, 2017).

BET INHIBITORS MAY REDUCE PARP INHIBITOR RESISTANCE POSSIBLY BY PREVENTING THE INDUCTION OF ALTERNATIVE DNA REPAIR PATHWAYS



41

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Drugzone Pharmaceuticals Inc.

Physical Address: 105 Airport Executive Park

City: Nanuet State: NY Zip: 10954

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-695-2894 Website: N/A

Name of Designated Representative (DR): Binu Baby

Licensing Company Email: compliance.drugzone@gmail.com DR Email: compliance.drugzone@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Full Service

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/9/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached vendor list

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): N/A

Corporation/Organization Name: Drugzone Pharmaceuticals Inc.

Mailing Address: 105 Airport Executive Park

City: Nanuet State: NY Zip: 10954

Telephone: 516-695-2894 Email: compliance.drugzone@gmail.com

Contact Person Name: Binu Baby

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Drugzone Pharmaceuticals Inc.

Facility Name

Binu Baby

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/9/24

Date

Board Use Only	Date Received: 10/7/24	Amount: $1000 CK 13180

NABP ACCREDITED

DRUG DISTRIBUTOR

Drugzone Pharmaceuticals Inc.

located at

105 Airport Executive Park, Nanuet, NY 10954

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

03-01-2022 to 02-28-2025
Period of Accreditation

Ownership Information

Drugzone Pharmaceuticals Inc.
105 Airport Executive Park
Nanuet, NY 10954

Owner: Binu Baby (100%)

Title: President

Address (Home): [redacted]

Address (Business): 105 Airport Executive Park, Nanuet, NY 10954

Phone Number (Home): [redacted]

Phone Number (Business): 516-695-2894

Social Security Number: [redacted]

Date of Birth: [redacted]

Drugzone Pharmaceuticals Inc.
Vendor List

DBC Pri-Med, LLC

111 Huntington Avenue, Boston MA 02199-7607

Oak Drugs, Inc.

80 Red Schoolhouse Road, Chestnut Ridge, NY 10977

Richie Pharmacal Company

119 State Ave, Glasgow, KY 42141

Independent Pharmacy Distributor

703 S. Salisbury Street, Lexington, NC 27292

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	DRUGZONE PHARMACEUTICALS INC
DOS ID Number:	5523478
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	03/28/2019
Statement Status:	CURRENT
Statement Due Date:	03/31/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on October 22, 2024 at 01:45 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006802203 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2022-25

NAME OF SUPERVISOR
BINU BABY

THIS IS TO CERTIFY

DRUGZONE PHARMACEUTICALS INC
105 AIRPORT EXECUTIVE
PARK
NANUET, NY 10954

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF NOVEMBER, 2022.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF OCTOBER, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
037764

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. L253877-2114

Application/License No. _____

Drugzone Pharmaceuticals, Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 105 Airport Executive Park, Nanuet, NY 10954 (Address of Applicant/Principal), as PRINCIPAL, and Lexington National Insurance Corporation (Surety Company), a corporation organized under the laws of the state of FL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 11426 York Road 2nd Floor Cockeysville, MD 21030 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/15/2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of June, 20 22.

Drugzone Pharmaceuticals, Inc

Authorized Representative

Lexington National Insurance Corporation

Surety Company's Representative

Valerie Aber, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

IMPORTANT NOTICE – THIS POWER OF ATTORNEY IS VOID IF "LNIC Original" WATERMARK IS NOT PRESENT

POWER OF ATTORNEY
Lexington National Insurance Corporation

Lexington National Insurance Corporation, a corporation duly organized under the laws of the State of Florida and having its principal administrative office in Baltimore County, Maryland, does hereby make, constitute and appoint:

Daniel Ruggeri and Valerie Aber

as its true and lawful attorney-in-fact, each in their separate capacity, with full power and authority to execute, acknowledge, seal and deliver on its behalf as surety any bond or undertaking of $6,000,000 or less. This Power of Attorney is void if used for any bond over that amount.

This Power of Attorney is granted under and by authority of the following resolutions adopted by the Board of Directors of the Company on February 15, 2018:

Be it Resolved, that the President or any Vice-President shall be and is hereby vested with full power and authority to appoint suitable persons as Attorney-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on the behalf of the Company, to execute, acknowledge and deliver any and all bonds, contracts, or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any all notices and documents cancelling or terminating the Company's liability thereunder and any such instruments so executed by any Attorney-in Fact shall be binding upon the Company as if signed by the President and sealed by the Corporate Secretary.

RESOLVED further, that the signature of the President or any Vice-President of LEXINGTON NATIONAL INSURANCE CORPORATION may be affixed by facsimile to any power of attorney, and the signature of the Secretary or any Assistant Secretary and the seal of the Company may be affixed by facsimile to any certificate of such power, or any such power or certificate bearing such facsimile signature or seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed with respect to any bond to which it is attached continue to be valid and binding upon the Company.

IN WITNESS WHEREOF, the Company have caused this instrument to be signed and their corporate seal to be hereto affixed.

Ronald A. Frank, President

LEXINGTON NATIONAL INSURANCE CORP. INCORPORATED 1989 FLORIDA

State of Maryland
County of Harford County, SS:

Before me, a notary public, personally appeared, Ronald A. Frank, President of Lexington National Insurance Corporation, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under the PENALTY of PERJURY under the laws of the State of Maryland that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Commission Expires: 05/23/24

Notary

ALYSSA BARNES NOTARY PUBLIC HARFORD COUNTY

I, Lisa R. Slater, Secretary of Lexington National Insurance Corporation, do hereby certify that the above and foregoing is true and correct copy of a Power of Attorney, executed by said company, which is still in full force and effect; furthermore, the resolutions of the Boards of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Baltimore, Maryland this 1st day of January, 2022.

Corporate Seal:

Lisa R. Slater, Secretary

Attached to bond signed this 15 day of June, 20 22

F:\lnic\Power of Attorney form CS 2021 with Watermark Seal

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Drugzone Pharmaceuticals Inc.

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 105 Airport Executive Park

City: Nanuet State: NY Zip: 10954

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-695-2894 Website: N/A

Licensing Company Email: compliance.drugzone@gmail.com

Section 2: Personal Information

First: Binu Middle: _____ Last: Baby

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 105 Airport Executive Park

City: Nanuet State: NY Zip: 10954

Telephone: 516-695-2894 Email: compliance.drugzone@gmail.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
H.SHIVALINGAPPA HIGH SCHOOL SAGAR		1990-1992	
Address	**City**	**State**	**Zip**
Shimoga	Karnataka	INDIA	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
KLE College of Pharmacy		1992-1996	
Address	**City**	**State**	**Zip**
948F+M2W, Hubli - Dharwad Hwy, Vidya Nagar, Hubballi,	Karnataka	INDIA	
Diploma/Degree obtained, if any			
Pharmacist School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
			10954
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/17-Present	[redacted]	Blauvelt	NY	10913
From - To (MM/YY – MM/YY)		City	State	Zip
06/02-09/17		Valley College	NY	10989
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Drugzone Pharmaceuticals Inc.			03/19-Present	
Business Address		**City**	**State**	**Zip**
105 Airport Executive Park		Nanuet	NY	10954
Phone	**Title**		**Number of Employed Hours**	
516-695-2894	Owner		46,098	

Description of Duties

Develop New Business and maintain existing business relationships.Provide ongoing strategic recommendations, training and coaching to provider groups & pharmacies on program implementation and barrier resolution.Stocking

Business Name			From - To (MM/YY – MM/YY)	
Justin Pharmacy			06/04-10/19	
Business Address		**City**	**State**	**Zip**
3860 Broadway		New York	NY	10032
Phone	**Title**		**Number of Employed Hours**	
212-923-6111	Owner/Supervisor Pharmacist		134,400	

Description of Duties

Manage the financial strength,productivity and organizational development within the pharmacy. Ensured policies and procedures were practiced universally. Set weekly and monthly goals for staff. Provided training,mentoring and feedback

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

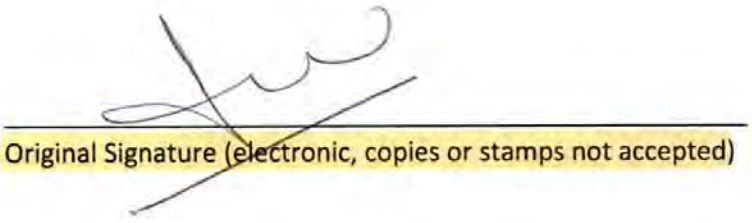
Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

7/9/2024

Date

I, Binu Baby, **certify that as the designated representative for**

Drugzone Pharmaceuticals Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BB I am at least 21 years of age;
3. BB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Binu Baby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Binu Baby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Rockland

I, Binu Baby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/9/24

Date

Subscribed and Sworn to before me this 9 day of July 2024.

Irene S Bot

Notary Public Signature

IRENE S BOTSCHAGOW
NOTARY PUBLIC, STATE OF NEW YORK
Registration No 01BO6391077
Qualified in Orange County
My Commission Expires: 5/13/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Drugzone Pharmacueticals Inc.

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 105 Airport Executive Park

City Nanuet State NY Zip 10954

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 516-695-2894 Website N/A

Licensing Company Email compliance.drugzone@gmail.com

Section 2: Personal Information

First Binu Middle _____ Last Baby

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 105 Airport Executive Park

City Nanuet State NY Zip 10954

Telephone 516-695-2894 Email binu@drugzone.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
H.SHIVALINGAPPA HIGH SCHOOL SAGAR			1990-1992	
Address	**City**		**State**	**Zip**
Shimoga	Karnataka		INDIA	
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
KLE College of Pharmacy			1992-1996	
Address	**City**		**State**	**Zip**
948F+M2W, Hubli - Dharwad Hwy, Vidya Nagar, Hubballi,	Karnataka		INDIA	
Diploma/Degree obtained, if any				
Pharmacist School				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	**City**		**State**	**Zip**
				10954
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/17-Present	[redacted]	Blauvelt	NY	10913
06/02-09/17		Valley College	NY	10989

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Drugzone Pharmacueticals Inc			03/19-Present
Business Address	**City**	**State**	**Zip**
105 Airport Executive Park	Nanuet	NY	10954
Phone	**Title**		
516-695-2894	Owner		

Description of Duties

Develop New Business and maintain existing business relationships.Provide ongoing strategic recommendations, training and coaching to provider groups & pharmacies on program implementation and barrier resolution.Stocking

Business Name			From - To (MM/YY – MM/YY)
Justin Pharmacy			06/04-10/19
Business Address	**City**	**State**	**Zip**
3860 Broadway	New York	NY	10032
Phone	**Title**		
212-923-6111	Owner/Supervisor Pharmacist		

Description of Duties

Manage the financial strength,productivity and organizational development within the pharmacy. Ensured policies and procedures were practiced universally. Set weekly and monthly goals for staff. Provided training,mentoring and feedback

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/9/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Binu Baby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Rockland

I, Binu Baby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/9/2024

Date

Subscribed and Sworn to before me this 9 day of July 2024.

Irene S Botschagow

Notary Public Signature

IRENE S BOTSCHAGOW
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01BO6391077
Qualified in Orange County
My Commission Expires. 5/13/2027

(Seal)

Drugzone Pharmaceuticals Inc.
Employee List

Binu Baby – sole employee indebted to applicant

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

PHARMACY INSPECTION REPORT ☐ Pharmacy ☒ M/W

Inspection # _____ conducted by
Investigator David Buckley
Date 10-17-17 Time In/Out _____ / _____

1. Routine
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
6. Medication Recall
7. Complaint Related
8. Follow-up to Previous Inspection
9. Special Project or Renovation

Reg. name Drug Zone Pharmaceuticals Inc
Trade name _____
No. and Street 125 Airport Executive Park
City Nanuet County Rockland Zip 10954
Reg. # _____ Telephone _____
Hours open per week 40 # RXs daily _____

Pharmacists' Names	Hrs. Per Week	License Number	License Date	License Displayed	Registration Displayed
S.P. Bina Baby	40	047837	11-7-00	(Y) N	(Y) N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Intern				Y N	Y N

Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below.
Be sure to include item number in explanation.

1. Registration name on exterior ..... (S) N
2. Licenses/current reg. displayed ..... (S) N
3. Registered pharmacist on duty ..... (S) N
4. Equip., facilities, and ref. items ..... (S) N
5. Price list available/current ..... S N
6. Drug stock current ..... S N
7. Stock properly branded ..... S N
8. Daily RX record ..... S N
9. Required RX filings ..... S N
10. DEA records complete/available ..... S N
11. Safety/approp. closures/containers ..... S N
12. RX labels required information ..... (S) N
13. Valid RX formats ..... S N
14. Substitution law compliance ..... S N
15. Required information on RXs ..... S N
16. Refill authorization/fill ..... S N
17. Refills in daily record ..... S N
18. Controlled substance compliance ..... S N
19. General sanitation ..... (S) N
20. Intern/unlicensed supervision ..... (S) N
21. Counseling offered/given/refusals documented ..... S N
22. Types of pharmacy (circle those applicable): retail, hospital, skilled nursing, assisted living, compounding, sterile preparation, Internet, home delivery, mail delivery, nuclear, veterinary

SL. open storage

Details of Inspection Conducted New Registration inspection. Present is Bina Baby. Store is currently empty. Shelving in place. Heat + AC working. Hot+Cold water available. Bathrooms in non-registered area. Fire & Intrusion Security system covers all exterior access/egress pts including windows. No Security films (Window) or bars in place. No controlled substances anticipated. Questions answered. Inspection Completed. Letter Attached

Recommendation (completed in office)
Investigator _____
Supervisor _____

I have received a copy of this inspection report.
Signature _____
Print name Bina Baby
Title Licensed Pharmacist Date 10/17/17

This is page _____ of _____ page(s)

OPD 234 (6/2011) 11-005 CDC ORIGINAL - TO CENTRAL OFFICE

4J

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02869	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Specialty Care Distribution

Physical Address: 4295 E. Jurupa St , Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Name of Designated Representative (DR): Cheryl Krueger

Licensing Company Email: licensing@rphpartners.net DR Email: ckrueger@rphpartners.net

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Cheryl Krueger
Original Signature (electronic, copies or stamps not accepted)

12/03/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson Plasma & Biologics
Address: 6555 N. State Highway 161 City: Irving State: TX Zip: 75039

Name: Genentech
Address: 1 DNA Way City: San Francisco State: CA Zip: 94080

Name: Sanofi
Address: 450 Water St City: Cambridge State: MA Zip: 02142

Name: Takeda
Address: 500 Kendall St City: Cambridge State: MA Zip: 02142

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California RPH Partners, Inc. dba Specialty Care Distribution
Parent Company (if any):
Corporation/Organization Name: RPH Partner, Inc. dba Specialty Care Distribution
Mailing Address: 4295 E. Jurupa St, Suite 102
City: Ontario State: CA Zip: 91761
Telephone: 909-687-7005 Email: ckrueger@rphpartners.net
Contact Person Name: Cheryl Krueger

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/			✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/			✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	N/A	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓		✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓		✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	N/A	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	N/A	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		N/A	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		N/A	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

RPH Partners, Inc. dba Specialty Care Distribution
Facility Name

Cheryl Krueger
Print Name of Authorized Person Submitting Application

Cheryl Krueger
Original signature of Authorized Person (copies or stamps not accepted)

12/03/2024
Date

Board Use Only	Date Received: 12/10/24	Amount: $1000-CK1759

NABP ACCREDITED
DRUG DISTRIBUTOR

RPH Partners, Inc. dba Specialty Care Distribution

located at

4295 E Jurupa St, Ste 102, Ontario, CA 91761

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/26/2024 - 04/25/2027
Period of Accreditation

RPH

4295 E JURUPA ST., STE 102
Ontario, CA 91761
T (909) 687-7005

Nevada Board of Pharmacy

RPH Partners, Inc. dba Specialty Care Distribution Lic # WH02869
List of Officers & Directors

Jeffrey S. Griffith – CEO

Brenda A. Brown – CFO/Secretary

Bhav G. Patel – Shareholder

Yatinkumar A. Patel – Shareholder

Cheryl A. Krueger – Supply Chain Director

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	RPH PARTNERS, INC.
Entity No.:	3781504
Registration Date:	04/27/2015
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of December 19, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 277019529

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **RPH PARTNERS, INC** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/24/2022, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/29/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202411295225391
You may verify this certificate online at https://www.nvsilverflume.gov/home



Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. WLS 6928
RECEIPT NO. 00192090

VALID UNTIL JUNE 01, 2025

SPECIALTY CARE DISTRIBUTION
4295 E JURUPA SUITE 102
ONTARIO CA 91761

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

14/24/24
14/24/24

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

SureTec Insurance Company

2103 CityWest Boulevard, Suite 1300 Houston, TX 77042

CONTINUATION CERTIFICATE

Bond No. 4438290
Principal: RPH Partners Inc. dba Specialty Care Distribution
Bond Amount: $ 100,000.00
Bond Description: Pharmaceutical Wholesale Distributor $25,000

Obligee: Nevada State Board of Pharmacy

You are hereby notified that the above Bond shall be continued in force for a period effective from:

May 13, 2024 until May 12, 2025

unless it is cancelled by the surety or otherwise terminated. All other terms and conditions remain unchanged.

The aggregate liability of the Surety shall not exceed the amount of this Continuation Certificate. The liability of the Surety shall not cumulate by reason of this Certificate, any Continuation Certificate, Change Rider, endorsement, modification, new bond, reinstatement, reissue, renewal, replacement, or substitution issued in the future.

Signed this 11th day of April , 2024 .

SureTec Insurance Company

By: _____
Arkadiy M. Lakshtanov, Attorney in Fact

RPH Partners Inc. dba Specialty Care Distribution

By: _____

POA #: 4438290

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Arkadiy M. Lakshtanov

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

Principal: RPH Partners Inc. dba Specialty Care Distribution
Obligee: Nevada State Board of Pharmacy
Amount: $ 100,000.00

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and of behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly sworn, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 128571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 11th day of April, 2024, A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power you may call (713) 812-0800 any business day between 8:30 am and 5:00 pm CST.

4295 E JURUPA ST., STE 102
Ontario, CA 91761
T (909) 687-7005

Nevada Board of Pharmacy

RPH Partners, Inc. dba Specialty Care Distribution Lic # WH02869
List of Corporate Shareholders

Jeffrey S. Griffith – CEO – 35%

Brenda A. Brown – CFO/Secretary – 35%

Bhav G. Patel – Shareholder – 21%

Yatinkumar A. Patel – Shareholder – 9%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Specialty Care Distribution

Physical Address: 4295 E. Jurupa St Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 909-687-7005 Website:

Licensing Company Email: licensing@rphpartners.net

Section 2: Personal Information

First: Cheryl Middle: Ann Last: Krueger

Alias(es, nicknames, name changes, etc.): Cheryl Ann Orosco

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Fontana State: CA Zip: 92337

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials: ck

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Duarte High School		9/1973 - 06/1977	
Address	**City**	**State**	**Zip**
1565 Central Ave	Duarte	CA	91010
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Chaffey College		10/2012 - 01/2015	
Address	**City**	**State**	**Zip**
5885 Haven Ave	Rancho Cucamonga	CA	91737
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2000 - present	[redacted]	Fontana	CA	92337
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials ck

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Specialty Care Distribution			082020 - present	
Business Address		**City**	**State**	**Zip**
4295 E. Jurupa St		Ontario	CA	91761
Phone	**Title**		**Number of Employed Hours**	
909-687-7206	Supply Chain Director/Designated Representative in Charge		8700	
Description of Duties				
Designated Representative in charge, forecast, purchase, ship & receive Rx drugs. Inventory control. Process recalls, create & implement policies and procedures, renew wholesale licenses, manage DSCSA				

Business Name			From - To (MM/YY – MM/YY)	
National Cornerstone Healthcare Services			04/2016 - 10/2017	
Business Address		**City**	**State**	**Zip**
24747 Redlands Blvd #B		Loma Linda	CA	92354
Phone	**Title**		**Number of Employed Hours**	
909-796-7608	Warehouse Manager		3320	
Description of Duties				
Designated Representative, forecast, purchase, ship & received Rx drugs. Inventory control, product disposition/recalls. Renew wholesale licenses.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials ck

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Chuck Krueger
Original Signature (electronic, copies or stamps not accepted)

12/03/2024
Date

I, Cheryl Ann Krueger, **certify that as the designated representative for**

RPH Partners, Inc. dba Specialty Care Distribution,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CK I am at least 21 years of age;
3. CK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cheryl Krueger

Print Name (First, Last)

Cheryl Krueger

Original Signature (electronic, copies or stamps not accepted)

10/03/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Krueger

Print Name (First, Last)

Cheryl Krueger

Original Signature (electronic, copies or stamps not accepted)

12/13/2024 12/03/2024

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of San Bernardino

I, Cheryl Krueger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cheryl Krueger

Original Signature

12/03/2024

Date

Subscribed and Sworn to before me this 3rd day of December, 2024

Notary Public Signature

LIDIA M. ROBERSON
Notary Public - California
San Bernardino County
Commission # 2467195
My Comm. Expires Nov 15, 2027

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

Applicant's initials ck

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: RPH Partners, Inc. dba Specialty Care Distribution

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 4295 E. Jurupa St, Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: licensing@rphpartners.net

Section 2: Personal Information

First: Jeffrey Middle: Scott Last: Griffith

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Carlsbad State: CA Zip: 92010

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
USC		1988-1991	
Address	City	State	Zip
	LOS ANGELES	CA	
Diploma/Degree obtained, if any			
BUSINESS ADMINISTRATION			

School Name		From - To (MM/YY – MM/YY)	
GLENDALE HIGH SCHOOL		1986-1988	
Address	City	State	Zip
	GLENDALE	CA	
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	CARLSBAD	CA	92010
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
RPH Partners, Inc.			2015 - Present	
Business Address		**City**	**State**	**Zip**
4295 E. Jurupa St, Suite 102		Ontario	CA	91761
Phone	**Title**			
760-525-3545	CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

11-26-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JEFF S. GRIFFITH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11.26.2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Jeffrey Scott Griffith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11.26.2024

Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Notary Certificate

Notary Public Signature

(Seal)

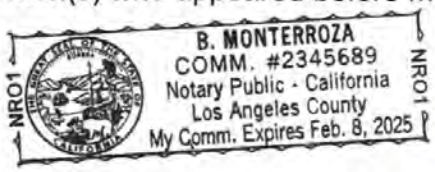
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 26TH day of NOVEMBER, 2024, by JEFFREY SCOTT GRIFFITH

---

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.



(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: RPH Partners, Inc. dba Specialty Care Distribution

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 4295 E. Jurupa St, Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: licensing@rphpartners.net

Section 2: Personal Information

First: Brenda Middle: Aurora Last: Brown

Alias(es, nicknames, name changes, etc.): Brenda Martinez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Frisco State: TX Zip: 75034

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FIDM		09/1994-06/1996	
Address	City	State	Zip
919 S. Grand Ave	Los Angeles	Ca	90015
Diploma/Degree obtained, if any			
Fashion Merchandise Marketing			

School Name		From - To (MM/YY – MM/YY)	
John F. Kennedy HS		09/1991-06/1994	
Address	City	State	Zip
11254 Gothic Ave	Granada Hill	Ca	91344
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2023- Present	[redacted]	Frisco	TX	75034
04/2017-08/2023		Calabasas	CA	91302
04/2012-04/2014		Sylmar	CA	91342
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SCRX LV			01/2017 - Present	
Business Address		**City**	**State**	**Zip**
8015 Rancho Dr		Las Vegas	NV	89106
Phone	**Title**			
(702) 478-5733	Officer			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
RPH			07/2015 - Present	
Business Address		**City**	**State**	**Zip**
4295 E. Jurupa St, Suite 102				
Phone	**Title**			
(909) 687-7064	Officer			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
SanFer Inc.				
Business Address		**City**	**State**	**Zip**
15257 Parthenia St.		North Hills	CA	91761
Phone	**Title**			
(818) 893-9971	Officer			
Description of Duties				
Management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

B.A.B.
Original Signature (electronic, copies or stamps not accepted)

11/25/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Branda Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Branda Brown, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/25/2024

Date

Subscribed and Sworn to before me this 25th day of November 2024

Desiree Vance

Notary Public Signature

DESIREE VANCE
Notary Public, State of Texas
Comm. Expires 06-20-2025
Notary ID 125427965

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: RPH Partners, Inc. dba Specialty Care Distribution

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 4295 E. Jurupa St, Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: licensing@rphpartners.net

Section 2: Personal Information

First: Bhav Middle: Girish Last: Patel

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bradbury State: CA Zip: 91008

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
La Salle High School		9/12-6/16	
Address	**City**	**State**	**Zip**
3880 E Sierra Madre Blvd	Pasadena	CA	91107
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
University of California, Los Angeles		9/16-6/20	
Address	**City**	**State**	**Zip**
420 Westwood Plaza	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
University of California, Los Angeles		9/20-6/21	
Address	**City**	**State**	**Zip**
420 Westwood Plaza	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
Masters of Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/23-Current	[redacted]	Bradbury	CA	91008
7/22-7/23		Arlington Heights	IL	60005
9/21-7/22		Annapolis	MD	21401
6/19-9/21		Bradbury	CA	91008
01/03-6/19		Los Angeles	CA	90041
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Healing Soul LLC			06/22-Current	
Business Address		**City**	**State**	**Zip**
40550 De Luz Murrieta Road		Fallbrook	CA	92038
Phone	**Title**			
	Member			
Description of Duties				
Directing construction project				

Business Name			From - To (MM/YY – MM/YY)	
Mammoth Lakes Hospitality LLC			06/23-Current	
Business Address		**City**	**State**	**Zip**
2445 Main Street		Mammoth Lakes	CA	
Phone	**Title**			
760-965-0544	Member			
Description of Duties				
Directing renovations				

Business Name			From - To (MM/YY – MM/YY)	
BA Hospitality Consulting LLC			11/23-Current	
Business Address		**City**	**State**	**Zip**
330 Mount Olive Drive		Bradbury	CA	91008
Phone	**Title**			
323-399-5958	Member			
Description of Duties				
Hospitality consulting chief				

Business Name			From - To (MM/YY – MM/YY)	
IVIGRx LLC			05/24-Current	
Business Address		**City**	**State**	**Zip**
21450 Golden Springs Drive, Suite 110		Diamond Bar	CA	91789
Phone	**Title**			
	Member			
Description of Duties				
Responsible for business strategy, growth, and operations				

Business Name			From - To (MM/YY – MM/YY)	
Casafusion LLC			4/24-Current	
Business Address		**City**	**State**	**Zip**
8 Rock Bluff Rd		Pomona	CA	91766
Phone	**Title**			
	Member			
Description of Duties				
Responsible for business strategy, growth, and operations				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/26/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bhav, Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/26/24

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached Notary Certificate

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 26TH day of NOVEMBER, 2024, by BHAV GIRISH PATEL

---

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

B. MONTERROZA
COMM. #2345689
Notary Public - California
Los Angeles County
My Comm. Expires Feb. 8, 2025

NRO1 NRO1

(Seal) Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: RPH Partners, Inc. dba Specialty Care Distribution

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 4295 E. Jurupa St, Suite 102

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: licensing@rphpartners.net

Section 2: Personal Information

First: Yatinkumar Middle: Amrutlal Last: Patel

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Pomona State: CA Zip: 91766

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University of Health Science		08/2006 - 12/2008	
Address	**City**	**State**	**Zip**
309 E 2nd St	Pomona	CA	91766
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of New South Wales		01/2004-12/2004	
Address	**City**	**State**	**Zip**
UNSW Sydney, High St Kensington NSW 2052 Australia	Sydney	NSW	2052
Diploma/Degree obtained, if any			
M.Sc. in Biopharmaceuticals			

School Name		From - To (MM/YY – MM/YY)	
Shri Sarvajanik Pharmacy College		08/1999-05/2003	
Address	**City**	**State**	**Zip**
J94R+6RJ, Sarvajanik Campus, Gujarat 384001, India	Mehsana	Gujarat	384001
Diploma/Degree obtained, if any			
B. Pharm.			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2013-current	[redacted]	Pomona	CA	91766
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Infusion For Health			12/2023-12/2024	
Business Address		**City**	**State**	**Zip**
11705 Slate Ave # 100		Riverside	CA	92505
Phone	**Title**			
951-499-4911	Pharmacist			

Description of Duties

Providing pharmacy service for specialty medications at home as well as company owned and operated infusion centers.-Review and process prior authorization requests for a wide range of medications, ensuring compliance with insurance policies and clinical guidelines

Business Name			From - To (MM/YY – MM/YY)	
Ayucare Infusion LLC			12/2023-current	
Business Address		**City**	**State**	**Zip**
16029 Arrow Hwy, Ste C,		Irwindale	CA	91706
Phone	**Title**			
626-542-7100	Pharmacist			

Description of Duties

Providing pharmacy service for specialty medications at home. Review and process prior authorization requests for a wide range of medications, ensuring compliance with insurance policies and clinical guidelines

Business Name			From - To (MM/YY – MM/YY)	
Prime Therapeutics , Magellan Health			03/2023-12/2023	
Business Address		**City**	**State**	**Zip**
2900 Ames Crossing Rd #200		Eagan	MN	55121
Phone	**Title**			
Remote	Pharmacist			

Description of Duties

Performed various duties related to the prior authorization of prescription orders and specialty medical utilization management. Worked in different markets of prior authorization Timely review prior auth requests to meet clients service level agreement. -Experience in reviewing prior auth for specialty, Part D, Part B

Business Name			From - To (MM/YY – MM/YY)	
OptumRX			08/2022-02/2023	
Business Address		**City**	**State**	**Zip**
11000 Optum Cir		Eden Prairie	MN	55344
Phone	**Title**			
Remote	Pharmacist			

Description of Duties

Performed various duties related to the prior authorization of prescription orders and specialty medical utilization management. Worked in different markets. Timely review prior auth requests to meet clients service level agreement. -Experience in reviewing prior auth for specialty, Part D, Part B drugs/supplies.

Business Name			From - To (MM/YY – MM/YY)	
Optum Infusion LLC			05/2018-07/2022	
Business Address		**City**	**State**	**Zip**
4900 Rivergrade Rd, Ste E120		Irwindale	CA	91706
Phone	**Title**			
626-257-9770	Pharmacist-in-Charge			

Description of Duties

Managed as pharmacist for Hemophilia, IVIG, Sub-q IG, TPNs, IV ATBx, Pain management hospice care, Specialty meds such as Tysabri, Entyvio, Remicade, Ocrevus, Actemra, Rituxan, Reclast, Hyqvia, Zemaira, Glassia and many more specialty infusion therapy. TPNs, IV ATBx, IV fluid with electrolytes, CADD cassette, multidose

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Coram HealthCare			10/2017-04/2018
Business Address	**City**	**State**	**Zip**
4355 E Lowell St,	Ontario	CA	91761
Phone	**Title**		
909-605-0010	Pharmacist		

Description of Duties

Managed as pharmacist for Hemophilia, IVIG, Sub-q IG, TPNs, IV ATBx, Pain management hospice care, Specialty meds such as Tysabri, Entyvio, Remicade, and many more specialty infusion therapy. TPNs, IV ATBx, IV fluid with electrolytes, CADD cassette Elastomeric pumps, IV-push Syringes under USP 797 and USP 800

Business Name			From - To (MM/YY – MM/YY)
Modern Healthcare			09/2011-09/2017
Business Address	**City**	**State**	**Zip**
110 E Huntington Dr	Monrovia	CA	91016
Phone	**Title**		
626-932-1600	Pharmacist		

Description of Duties

Overseen Infusion Services department for performance, training and IV skills

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/03/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yatinkumar Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/03/24

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of SAN BERNARDINO

I, Yatinkumar Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/03/24

Date

Subscribed and Sworn to before me this 03 day of DECEMBER, 2024

Notary Public Signature

KALPIT PARIKH
Notary Public - California
San Bernardino County
Commission # 2483236
My Comm. Expires Feb 27, 2028

(Seal)

CALIFORNIA ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of SAN BERNARDINO }

On 12/03/24 before me, KALPIT PARIKH, NOTARY PUBLIC
Date *Here Insert Name and Title of the Officer*

personally appeared YATINKUMAR PATEL
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

KALPIT PARIKH
Notary Public - California
San Bernardino County
Commission # 2483236
My Comm. Expires Feb 27, 2028

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____
☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator
☐ Other: _____
Signer is Representing: _____

Signer's Name: _____
☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator
☐ Other: _____
Signer is Representing: _____

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RPH

4295 E JURUPA ST., STE 102
Ontario, CA 91761
T (909) 687-7005

Nevada List of Applicant Indebtedness

Employees

Cheryl Krueger

Stephen Francis

Agent- Sadhana Maline

Independent Contractor – None

Consultant – None

Personal Representative – None

Lender or Holder of Indebtedness - None

4K

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located? New York	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: VET4U, LLC

Physical Address: 4155 Route 31, Suite 2

City: Clay State: NY Zip: 13041

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-794-2360 Website: www.vet4urx.com

Name of Designated Representative (DR): Patrick S. DiMauro

Licensing Company Email: pdimauro@vet4urx.com DR Email: pdimauro@vet4urx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☒ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Clinics + Gov't Agencies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1.31.2024	N/A	MD	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Maryland Board of Pharmacy		
Reason/Charge				
Voluntary license surrender				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
VET4U, LLC				

Provide explanation below:

VET4U, LLC, located at 7020 Fly Rd. Suite 3 East Syracuse, NY 13057, voluntarily surrendered Maryland distributor license #D07130 on January 31, 2024.

This voluntary surrender is the result of 3 failed attempts to get adequate fingerprints to complete the required background check for license renewal. To avoid expiration, the decision was made to voluntarily surrender with intention to reapply.

Original Signature (electronic, copies or stamps not accepted)

5-6-2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson
Address: 2700 North America Ave. City: West Seneca State: NY Zip: 14224

Name: AmerisourceBergen
Address: 6001 Global Distribution Way Ste 102 City: Louisville State: KY Zip: 40228

Name: R+S Northeast LLC
Address: 10049 Sandmeyer Ln. City: Philadelphia State: PA Zip: 19116

Name: Parmed Pharmaceuticals
Address: 5960 E. Shelby Dr. Ste 100 City: Memphis State: TN Zip: 38141

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): N/A
Corporation/Organization Name: VET4U, LLC
Mailing Address: 4155 Route 31, Suite 2
City: Clay State: NY Zip: 13041
Telephone: 888-794-2360 Email: pdimauro@vet4urx.com
Contact Person Name: Patrick S. DiMauro

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: In process		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

VET4U, LLC

Facility Name

Patrick S. DiMauro

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8-6 2024

Date

Board Use Only	Date Received: 8/21/24	Amount: $1000 - CH0100090 ✓

NABP ACCREDITED
DRUG DISTRIBUTOR

VET4U, LLC

located at

4155 Route 31, Ste 2, Clay, NY 13041

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

08/12/2024 - 08/11/2025
Period of Accreditation

VET4U, LLC
4155 Route 31 Ste 2 Clay, NY 13041
FEIN: 27-0636421

Officer List

Raymond J. Davis, Managing Member
DOB: [redacted]
Address: [redacted]
[redacted]
51% ownership

Patrick S. DiMauro, Member
DOB: [redacted]
Address: [redacted]
[redacted]
49% ownership

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	VET4U, LLC
DOS ID Number:	4093251
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Entity Status:	EXISTING
Date of Initial Filing with DOS:	05/11/2011
Statement Status:	CURRENT
Statement Due Date:	05/31/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on May 01, 2024 at 03:24 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100005654854 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
RENEE A. AINSWORTH

THIS IS TO CERTIFY

VET4U, LLC
4155 ROUTE 31
SUITE 2
CLAY, NY 13041

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-THIRD DAY OF MAY, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTIETH DAY OF APRIL, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

040904

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

NEW YORK STATE DEPARTMENT OF HEALTH
CONTROLLED SUBSTANCE LICENSE

Class: 020
DISTRIBUTOR

VET4U LLC
4155 ROUTE 31 SUITE 2
CLAY, NY 13041

Licensed Location:
VET4U LLC
4155 ROUTE 31 SUITE 2
CLAY, NY 13041

Schedule:
II III IV V

HAS GIVEN SATISFACTORY EVIDENCE THAT ALL QUALIFICATIONS AS REQUIRED BY ARTICLE 33 OF THE PUBLIC HEALTH LAW AND PART 80 OF THE ADMINISTRATIVE RULES AND REGULATIONS HAVE BEEN MET AND IS HEREBY GRANTED A LICENSE TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY IN THE STATE OF NEW YORK IN THE CLASSIFICATION STATED ABOVE.

LICENSE #: 0200429
EFFECTIVE: Jul 09 2024
EXPIRES: Jul 08 2026

JAMES V. McDONALD, M.D., M.P.H.,
COMMISSIONER OF HEALTH

TO BE PERMANENTLY DISPLAYED AT THE LICENSED SITE

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RV0582444	05-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	04-10-2024

VET4U, LLC
VET4U, LLC
7020 FLY RD STE 3
EAST SYRACUSE, NY 130579653

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RV0582444	05-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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VET4U, LLC
VET4U, LLC
7020 FLY RD STE 3
EAST SYRACUSE, NY 130579653

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RV0582444	05-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	04-10-2024

VET4U, LLC
VET4U, LLC
7020 FLY RD STE 3
EAST SYRACUSE, NY 130579653

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2012

VET4U, LLC

4155 Route 31 Ste 2 Clay, NY 13041

FEIN: 27-0636421

DEA License Statement

VET4U, LLC was informed by the DEA Diversion Investigator assigned to the Central New York region, Larry Martin, that prior to the inventory changing location, the DEA Diversion Investigator would do a complete inspection of the new facility. Additionally, Investigator Martin advised that upon the day of relocating the controlled substances to the new facility, VET4U is to contact him, and he will change the address on the current DEA Certificate to the new facility address but a new certificate would not be issued.

BOND RIDER

To be attached to and form a part of Bond No. 0814935
Dated the 2nd Day of February 2022 By and Between:
VET4U, LLC, as Principal and
Harco National Insurance Company as Surety, in favor of
Nevada State Board of Pharmacy, as Obligee.

It is understood and agreed that the bond is changed or revised in the particulars checked below:

☐ Name of Principal changed to:

_____

_____

☐ Amount of Bond changed from: _____
To _____

☒ Other: Address to be read as: 4155 Route 31, Suite 2, Clay, NY 13041

Said bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified. The bond Rider shall become effective as of 7/31/2024.

IN WITNESS WHEREOF, HARCO NATIONAL INSURANCE COMPANY has caused its corporate seal to be hereunto affixed this 1st day of August, 2024.

HARCO NATIONAL INSURANCE COMPANY

By: _____
Attorney-in-Fact Sharif Ismail

POWER OF ATTORNEY

Bond # 0814935

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

RALF RIGO, SHARIF ISMAIL

Syracuse, NY

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, August 01, 2024

A00816

Irene Martins, Assistant Secretary

PATRICK S. DiMAURO
[redacted]
Manlius, New York 13104
[redacted]

PROFESSIONAL OVERVIEW

Over thirty years of progressive leadership experience with profitable, dynamic growth-oriented organizations. Senior management team member with proven expertise in the areas of leadership, strategic planning, general management, budgeting, general administrative functions, facilities management, and human resources.

EXPERIENCE

Member

VET4U, LLC, Syracuse, NY, 7/09-present

4/16-present- Responsible for the start- up of a wholesale pharmaceutical distributorship selling to governmental entities and non-governmental entities.

- Developed contractual relationships with over fifteen manufacturers of pharmaceuticals
- Responsible for securing individual state wholesale pharmaceutical licenses resulting in being able to distribute pharmaceutical in over forty (40) states

07/09-4/16 - Responsible for the on-going management of commercial construction company

- Increase annual sales from start up to $2.5 million in annual construction revenue
- Implemented an integrated project delivery program that resulted in on-time on budget projects with open communications between all parties involved in the construction process

Director of Operations

Hueber-Breuer Construction Co., Inc., Syracuse, NY, (8/02-12/13)

Responsible for the areas of Risk Management, Contract Administration, Safety, Field Administration, Special Projects, and Human Resources.

- Reduced overall costs of insurances over four years by 35% resulting in direct bottom line savings through the implementation of risk transfer programs.
- Increased direct labor hourly rate margin by 33% through the thorough analysis of all cost components.
- Implemented onsite superintendent training programs that resulted in increased project profits
- Responsible for the refinancing of a commercial project resulting in annual cash flow increases of over $500,000 in addition to securing full guarantee of tenant.
- Implemented field safety and accountability programs that resulted in the continual reduction of the workers' compensation mod and having a positive bottom-line impact.
- Implemented project management software that increased communication between field, architect, and owner that resulted in reducing the construction schedule and increasing margins.

Vice President of Operations

David J Hardy Construction Company, Inc. Syracuse, NY (1997-present)

Responsible for the areas of Estimating, Construction, Warehousing/Inventory Control, Human Resources and Administration.

- Increased annual sales from $13 million to over $42 million in four years through the implementation of annual goal setting planning programs for all division and department heads.
- Implemented management-training programs for field managers that resulted in increased profitability on each job.
- Implemented employee relations programs that reduced turnover to below ten percent annually.
- Implemented a performance appraisal program for all levels of employees that identified top performers and career paths for future opportunities.
- Developed and implemented a company wide benefits program that reduced costs by over fifteen percent while providing overall better coverages.
- Developed and implemented a company-wide safety program that resulted in multiple year reductions in our workers compensation mod and dividends received totaling over $400,000.

Director of Administration and Human Resources
CIS Corporation, Syracuse, NY (1994-1997)
Responsible for the areas of Human Resources, facilities, security, and risk management.

- Developed and implemented a strategic business plan for the telecommunications division that resulted in attaining record sales and earnings.
- Implemented a new benefits program that reduced costs by over twenty percent while enhancing the overall program.
- Reduced facilities budgets by over thirty percent through the evaluation of all contractual commitments through renegotiation.
- Project manger for plant closing that resulted in meeting all deadlines and coming in under budget with a saving of $750,000.

Owner/President
Patrick & Co., Aussie Outfitters, Syracuse, NY (1994-1998)
Developed and implemented a strategic business plan for a retail apparel store. Responsible for the ongoing management.

- Stores consistently ranked in the top ten in the nation.
- Have been used in a consulting role by Aussie Outfitters for future expansions and new owners.

Director
Pyramid Companies, Syracuse, NY (1989-1994)
Responsible for the development and implementation of the strategic plans for an eighteen regional shopping center management company including, field management, marketing, market research, organizational development, human resources, and training.

- Developed and implemented a business plan approach for general managers that resulted in five years of exceeding organizational goals and becoming an industry leader.
- Implemented business training initiative of field management personnel that prepared employees for future opportunities while supporting and enhancing the business goals of the organization.
- Developed and implanted a merchant/customer relations program that created a partnership in the attainment of overall goals.
- Continual reduction of overhead costs through the training of field management in all areas of the business and by working with vendors.
- Directed an anti union campaign that resulted in the organization remaining union free.
- Implemented market research training programs that enabled field management to become an integral part of the sales and leasing effort.
- Designed incentive plans for all employees to ensure goals are met through increased company savings and/or profit generation.

Administrative Vice President/ Executive Officer, Human Resources
Key Bank of Central New York, Syracuse, NY (1985-1989)
Responsible for total Human Resource function for $2.3 billion organization with over 1400 employees.

EDUCATION/PROFESSIONAL DEVELOPMENT

State University College at Oswego, Graduate Work
State University College at Buffalo, Master of Science, Bachelor of Science
OSHA Thirty Hour
Incentive Based Compensation Programs
American Compensation Association, Los Angeles, Calif.
International Compensation, ACA Certified
American Compensation Association, Los Angeles, Calif.
Wage and Salary Administration
Society for Human Resource Management, New York
Employee Relations for the Non-Union Employer

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler VET4U, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 4155 Route 31, Suite 2

City Clay State NY Zip 13041

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-794-2360 Website www.vet4urx.com

Licensing Company Email pdimauro@vet4urx.com

Section 2: Personal Information

First Patrick Middle S. Last DiMauro

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Manlius State NY Zip 13104

Telephone [redacted] Email pdimauro@vet4urx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Henninger High School			
Address	**City**	**State**	**Zip**
600 Robinson St.	Syracuse	NY	13206
Diploma/Degree obtained, if any			
Regents Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
State University of College at Buffalo			
Address	**City**	**State**	**Zip**
1300 Elmwood Ave.	Buffalo	NY	14222
Diploma/Degree obtained, if any			
Master of Science Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2003 - Present	[redacted]	Manlius	NY	13104
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
VET4U, LLC			07-09 - Present	
Business Address		**City**	**State**	**Zip**
7020 Fly Rd., Suite 3		East Syracuse	NY	13057
Phone	**Title**		**Number of Employed Hours**	
888-794-2360	Member		31,000+	
Description of Duties				
See attached resume.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1.31.2024	N/A	MD	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Maryland Board of Pharmacy		
Reason/Charge				
Voluntary license surrender				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
VET4U, LLC				

Provide explanation below:

VET4U, LLC, located at 7020 Fly Rd. Suite 3 East Syracuse, NY 13057, voluntarily surrendered Maryland distributor license #D07130 on January 31, 2024.

This voluntary surrender is the result of 3 failed attempts to get adequate fingerprints to complete the required background check for license renewal. To avoid expiration, the decision was made to voluntarily surrender with intention to reapply.

Original Signature (electronic, copies or stamps not accepted)

8-6-2024
Date

I, Patrick S. DiMauro, **certify that as the designated representative for**

VET4U, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PSD I am at least 21 years of age;
3. PSD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PSD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PSD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PSD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PSD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Patrick S. DiMauro
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-6-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patrick S. DiMauro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-6-2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Onondaga

I, Patrick S DiMauro, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-6-2024

Date

Subscribed and Sworn to before me this 6th day of August.

Notary Public Signature

RENEE ANNE AINSWORTH
Notary Public - State of New York
NO. 01AI6390019
Qualified in Onondaga County
My Commission Expires Apr 8, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site VET4U, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 4155 Route 31, Suite 2

City Clay State NY Zip 13041

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-794-2360 Website www.vet4urx.com

Licensing Company Email pdimauro@vet4urx.com

Section 2: Personal Information

First Patrick Middle S. Last DiMauro

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Manlius State NY Zip 13104

Telephone [redacted] Email pdimauro@vet4urx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Henninger High School			1964 - 1967	
Address		City	State	Zip
600 Robinson St.		Syracuse	NY	13206
Diploma/Degree obtained, if any				
Regents Diploma				
School Name			From - To (MM/YY – MM/YY)	
State University College of New York at Buffalo			1967 - 1972	
Address		City	State	Zip
1300 Elmwood Ave.		Buffalo	NY	14222
Diploma/Degree obtained, if any				
Master of Science Degree				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2003 - Present	[redacted]	Manlius	NY	13104
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
VET4U, LLC				
Business Address		**City**	**State**	**Zip**
7020 Fly Rd., Suite 3		East Syracuse	NY	13057
Phone	**Title**			
888-794-2360	Member			
Description of Duties				
See attached resume.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1.31.2024	N/A	MD	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Maryland Board of Pharmacy		
Reason/Charge				
Voluntary license surrender				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
VET4U, LLC				

Provide explanation below:

VET4U, LLC, located at 7020 Fly Rd. Suite 3 East Syracuse, NY 13057, voluntarily surrendered Maryland distributor license #D07130 on January 31, 2024.

This voluntary surrender is the result of 3 failed attempts to get adequate fingerprints to complete the required background check for license renewal. To avoid expiration, the decision was made to voluntarily surrender with intention to reapply.

Original Signature (electronic, copies or stamps not accepted)

8-6-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patrick S. DiMauro
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-6-2024
Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Onondaga

I, Patrick S. DiMauro, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-6-2024
Date

Subscribed and Sworn to before me this 6th day of August.

Notary Public Signature

RENEE ANNE AINSWORTH
Notary Public - State of New York
NO. 01AI6390019
Qualified in Onondaga County
My Commission Expires Apr 8, 2027
(Seal)

Raymond J Davis
[redacted]
Fabius, NY 13063

[redacted]

PROFESSIONAL OVERVIEW

Over thirty years of leadership experience with profitable, dynamic growth-oriented organizations.
Owner, senior management team member with proven expertise in the areas of leadership, sales, strategic planning, budgeting, general administrative functions, and human resources.

EXPERIENCE

Managing Member
VET4U, LLC, Syracuse, NY 9/20 to present

Owner
RSK Enterprises LLC, Fayetteville, AR 01/01/2017
Worked as agent for VET4U, LLC
Responsible for initial set-up of Wholesale Pharmaceutical Distribution, selling to Government and non-government entities.

1. Developed contractual relationships with over fifteen manufactures of pharmaceuticals.
2. Hired sales force with pharmaceutical experience.
3. Identified customers and built relationships with customers.
4. Ensured product quality and delivery.
5. Managed the collection and payment of all accounts receivable and accounts payable.
6. Developed compensation plan for sales team.

Owner
Davis and Garrett Insurance, Fayetteville, AR 2007 - 2015
Worked as a licensed Insurance Agency. Sold agency in 2015
Responsible for all aspects of business ownership.

1. Hiring and training Insurance Agents
2. Accounting, AR, AP and commissions
3. Setting up contracts with Insurance providers.
4. Maintaining escrow accounts with customer's premiums.

Agent
Johnson, Moorman and Russell 1993
Licensed Insurance Agent
Responsible for maintaining Insurance License with State of Arkansas
Quoting and binding Insurance policies for Business customers.
Making sure policies had adequate coverages in place for the risk.
Top producer out of 200 agents.

U.S. Army
Combat Veteran
Operation Desert Storm 1990-1991
2/142d FA attached to the 1st Infantry Division
Joined U.S. Army National Guard in 1983 served also U.S. Army till 1991

EDUCATION

Lincoln High School 1983

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site VET4U, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 4155 Route 31, Suite 2

City Clay State NY Zip 13041

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-794-2360 Website www.vet4urx.com

Licensing Company Email pdimauro@vet4urx.com

Section 2: Personal Information

First Raymond Middle J. Last Davis

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Fabius State NY Zip 13063

Telephone [redacted] Email rdavis@vet4urx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lincoln High School		1977 - 1985	
Address	**City**	**State**	**Zip**
107 East School St.	Lincoln	AR	27244
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
No college attended.			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19 - Present	[redacted]	Fabius	NY	13063
01/92 - 09/19	[redacted]	Fayetteville	AR	72704
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
VET4U, LLC			09/20 - Present	
Business Address	**City**		**State**	**Zip**
7020 Fly Rd. Suite 3	East Syracuse		NY	13057
Phone	**Title**			
888-794-2360	Managing Member			
Description of Duties				
See attached resume.				

Business Name			From - To (MM/YY – MM/YY)	
VET4U, LLC			01-16 - 09/20	
Business Address	**City**		**State**	**Zip**
7020 Fly Rd. Suite 3	East Syracuse		NY	13057
Phone	**Title**			
888-794-2360	Sales + Marketing Director			
Description of Duties				
See attached resume.				

Business Name			From - To (MM/YY – MM/YY)	
Davis + Garrett Insurance			05/08 - 07/15	
Business Address	**City**		**State**	**Zip**
3789 N. Bellafont Blvd. Suite 1	Fayetteville		AR	72703
Phone	**Title**			
479-571-3500	Member			
Description of Duties				
See attached resume.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1.31.2024	N/A	MD	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Maryland Board of Pharmacy		
Reason/Charge				
Voluntary license surrender.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
VET4U, LLC				

Provide explanation below:

VET4U, LLC, located at 7020 Fly Rd. Suite 3 East Syracuse, NY 13057, voluntarily surrendered Maryland distributor license #D07130 on January 31, 2024.

This voluntary surrender is the result of 3 failed attempts to get adequate fingerprints to complete the required background check for license renewal. To avoid expiration, the decision was made to voluntarily surrender with intention to reapply.

Original Signature (electronic, copies or stamps not accepted)

6 Aug 24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Raymond J. Davis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6 Aug 24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Onondaga

I, Raymond J. Davis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6 Aug 24

Date

Subscribed and Sworn to before me this 6th day of August 2024

Notary Public Signature

RENEE ANNE AINSWORTH
Notary Public - State of New York
NO. 01AI6390019
Qualified in Onondaga County
My Commission Expires Apr 8, 2027

(Seal)

VET4U, LLC

4155 Route 31 Ste 2 Clay, NY 13041

FEIN: 27-0636421

Facility Employee List

Ray Davis- CEO

Patrick DiMauro- COO

Dan Bresnahan- VP Ops

Renee Ainsworth- CDR Florida, CDR California and Compliance

Maher Najjar- CIO

Branden Ort- Warehouse clerk/Forklift Operator

Konnor Frey- Warehouse Picker/Scanner

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* See Attachment A ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH00853	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bausch & Lomb Incorporated

Physical Address: 1501 Graves Mill Road

City: Lynchburg State: VA Zip: 24502

Mailing Address (if different from physical address): 32 Discovery, Suite 200, Attn: Sharath Gadasally

City: Irvine State: CA Zip: 92618

Telephone: 434-385-0407 Website: www.bausch.com

Name of Designated Representative (DR): Randall Morris

Licensing Company Email: statelicensing@bausch.com DR Email: statelicensing@bausch.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☑ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Own-label distributor

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No pharmaceuticals products are sold, dispensed, or distributed by this facility.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation N/A

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Bausch+Lomb Netherlands B.V.

Corporation/Organization Name: Bausch & Lomb Incorporated

Mailing Address: 32 Discovery, Suite 200, Attn: Sharath Gadasally

City: Irvine State: CA Zip: 92618

Telephone: 310-936-9542 Email: statelicensing@bausch.com

Contact Person Name: Sharath Gadasally

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: N/A		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bausch & Lomb Incorporated

Facility Name

Randall Morris

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8-28-2024

Date

Board Use Only	Date Received: 9/25/24	Amount: $1000 ck 1939

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Bausch & Lomb Incorporated
1501 Graves Mill Rd
Lynchburg, VA 24502
Registration Number: 1123818
FEI Number*: 1000305478
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information
Date Of Registration Status: 2024

Owner/Operator:
Bausch & Lomb Incorporated[6]
400 Somerset Corporate Blvd
Bridgewater, NJ US 08807
Owner/Operator Number: 9913003[7]

Official Correspondent:
Margaret Wood
400 Somerset Corporate Blvd
Bridgewater, NJ 08807
Phone: 864-3206017

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9913003&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9913003&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN

Page Last Updated: 08/26/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9913003&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9913003&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN

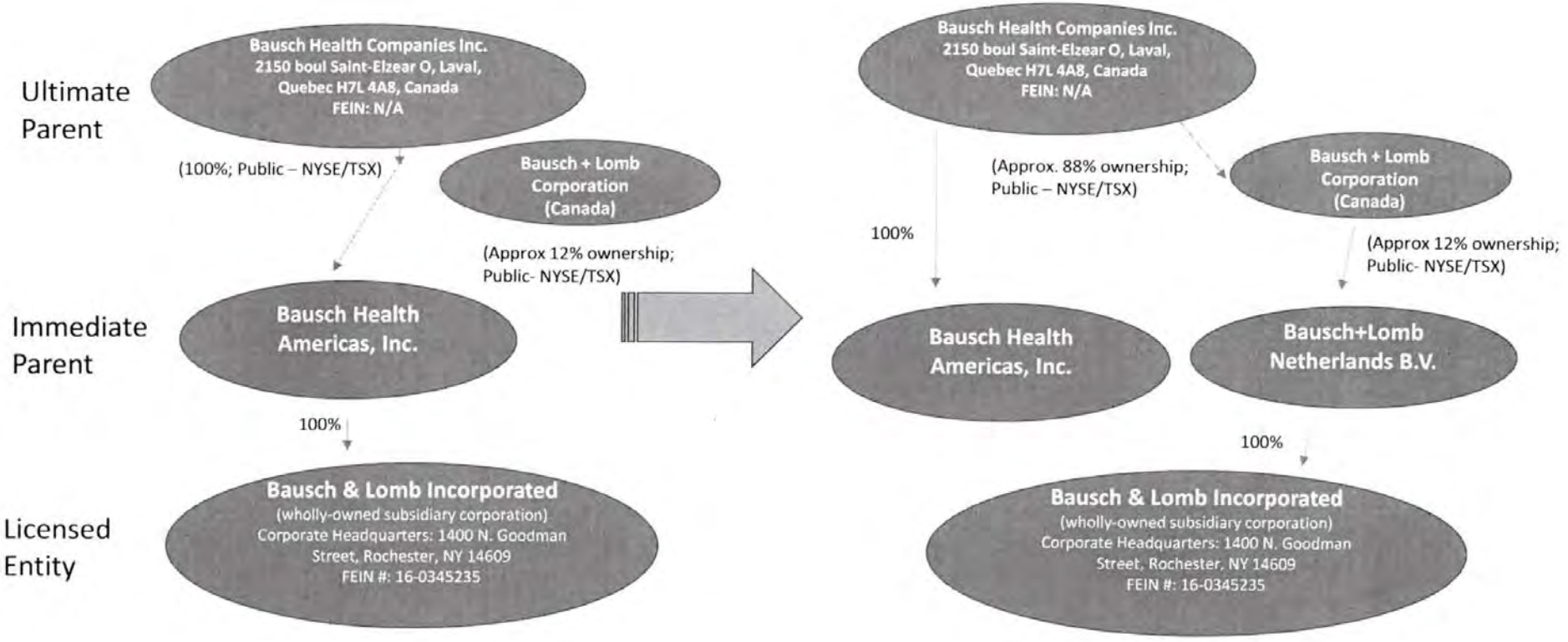
Attachment A

Regarding the Company Reorganization

Bausch & Lomb Incorporated (B&L) notifies the Board of an organizational structure change in its holding company from Bausch Health Americas, Inc. to Bausch+Lomb Netherlands B.V., a Netherlands entity, another indirect subsidiary of Bausch Health Companies Inc. Despite this change, please note that Bausch Health Companies Inc. (BHC Inc.) remains the ultimate corporate parent of B&L. Bausch Health Americas, Inc. remains an indirect subsidiary of BHC Inc. BHC Inc. remains the owner, accounting of approximately 88% of the equity interest of Bausch + Lomb Corporation.

This change results from a corporate restructure that only affects the immediate parent company of B&L while maintaining ultimate control and ownership with BHC Inc. **B&L remains a separate legal entity, with no changes in personnel or FEIN # as a result of this change.** Enclosed please find an organizational chart listing both immediate and ultimate parent and percentages of ownership/equity.

Bausch & Lomb Incorporated Organizational Change – No Change in Control



Attachment D

Corporate Officer Information

Bausch & Lomb Incorporated

Corporate Officers:

Donald A. Matheson
Vice President

John F. LaFave
Vice President

Attachment E

New York Certificate of Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	BAUSCH & LOMB INCORPORATED
DOS ID Number:	28631
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	03/20/1908
Statement Status:	CURRENT
Statement Due Date:	03/31/2024

I certify that the following is a list of documents on file in the Department of State for said entity:

Document Type:	CERTIFICATE OF INCORPORATION
Date of Filing:	03/20/1908
Entity Name:	BAUSCH & LOMB OPTICAL COMPANY

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/04/1908

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/16/1920

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	05/29/1928

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/30/1929
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/16/1935
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/17/1937
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/17/1937
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	02/25/1938
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	07/16/1945
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	10/01/1945
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	10/25/1948
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/27/1949
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	01/28/1958
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	03/31/1960
Name Changed To:	BAUSCH & LOMB INCORPORATED

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 06/03/1968

Document Type: CERTIFICATE OF MERGER
Date of Filing: 10/23/1968

Document Type: CERTIFICATE OF MERGER
Date of Filing: 11/21/1969

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/15/1970

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/12/1972

Document Type: CERTIFICATE OF MERGER
Date of Filing: 12/27/1973
Effective Date: 12/30/1973

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/03/1974

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 04/22/1976

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	04/22/1976
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	05/11/1979
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	09/11/1980
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	04/28/1981
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	06/27/1984
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	05/15/1985
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	09/13/1985
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	10/17/1988
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	06/25/1992
Document Type:	BIENNIAL STATEMENT
Date of Filing:	05/11/1993
Effective Date:	03/01/1993
Document Type:	BIENNIAL STATEMENT
Date of Filing:	04/26/1994
Effective Date:	03/01/1994

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/20/1998
Effective Date:	03/01/1998

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/23/2000
Effective Date:	03/01/2000

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/30/2001
Effective Date:	03/31/2001

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/18/2002
Effective Date:	03/01/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/19/2002
Effective Date:	12/28/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/19/2002
Effective Date:	12/28/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/09/2003
Effective Date:	12/27/2003

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/09/2003
Effective Date:	12/27/2003

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/15/2003
Effective Date:	12/27/2003

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/30/2004
Effective Date:	03/01/2004
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	04/26/2005
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	10/11/2005
Document Type:	BIENNIAL STATEMENT
Date of Filing:	04/14/2006
Effective Date:	03/01/2006
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	10/26/2007
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	11/01/2007
Document Type:	BIENNIAL STATEMENT
Date of Filing:	04/23/2008
Effective Date:	03/01/2008
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	07/02/2008
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/18/2010
Effective Date:	03/01/2010
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/08/2012
Effective Date:	03/01/2012

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	07/29/2013
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/03/2014
Effective Date:	03/01/2014
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/02/2016
Effective Date:	03/01/2016
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	03/22/2018
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/28/2018
Effective Date:	03/01/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/14/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/14/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/17/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/11/2019
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	09/06/2019
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	01/02/2020

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	01/23/2020
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/19/2020
Effective Date:	03/01/2020
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	02/08/2021
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/04/2022
Effective Date:	03/01/2022
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/17/2022
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	06/14/2023

Above space is left blank intentionally.

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 17, 2024 at 10:48 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100005015012 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Virginia Department of Health Professions
An official website Here's how you know

Virginia Department of Health Professions
License Lookup

Current as of 01/12/2024 09:50

License Information

License Number	0215000338
Occupation	Wholesale Distributor
Name	BAUSCH & LOMB, INC.
Address	Sharath Gadasally 1501 GRAVES MILL RD. Lynchburg, VA 24502
Initial License Date	04/01/2003
Expire Date	02/28/2025
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* *"Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

LISTING OF SECURITY FEATURES ON REVERSE SIDE

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

BOARD OF PHARMACY

Wholesale Distributor Permit

BAUSCH & LOMB, INC.

1501 GRAVES MILL RD.
Lynchburg VA 24502

Number
0215000338

To verify the status of this permit, visit our website www.dhp.virginia.gov, which is a primary source verification of the credential issued by the Commonwealth of Virginia. To File a Complaint About a Licensee, Call: 1-800-533-1560.

Attachment I

MDEG Administrator Form and Insurance Certificate

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/05/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA, LLC. 1166 Avenue of the Americas New York, NY 10036 030024--GAWUP-23-24	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED Bausch & Lomb Incorporated 1400 N. Goodman Street Rochester, NY 14609	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : ACE American Insurance Company — 22667 INSURER B : N/A — N/A INSURER C : N/A — N/A INSURER D : N/A — N/A INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** NYC-012038034-02 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			HDOG48898646	11/01/2023	11/01/2024	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER						MED EXP (Any one person)	$	10,000
	X POLICY PRO-JECT LOC						PERSONAL & ADV INJURY	$	2,000,000
	OTHER						GENERAL AGGREGATE	$	4,000,000
							PRODUCTS - COMP/OP AGG	$	EXCLUDED
								$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	$	
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of insurance for Bausch & Lomb Incorporated and its facilities, including but not limited to:
4011 Highway 417, Woodruff, SC 29388
1501 Graves Mill Road, Lynchburg, VA 24502
8500 Hidden River Pkwy, Tampa, FL 33637

CERTIFICATE HOLDER

Bausch & Lomb Incorporated d/b/a
Bausch & Lomb Americas, Inc
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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The ACORD name and logo are registered marks of ACORD

intact surety

CHANGE RIDER

To be attached to and form a part of Pharmaceutical Wholesaler Surety Bond

Bond No. 800140418 issued by **ATLANTIC SPECIALTY INSURANCE COMPANY**, 605 Highway 169 North, Suite 800, Plymouth, Minnesota, USA 55441 as Surety on behalf of Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604, as Principal in favor of State of Nevada and the Nevada State Board of Pharmacy with reference to Nevada Revised Statutes (NRS) 639.515 effective the 5th of August, 2022.

It is hereby understood and agreed that the following item is amended:

The addresses of the Principal doing or intending to do business as a pharmaceutical wholesaler, for purposes of services is amended to include the following sites:

- 1501 Graves Mill Road, Lynchburg, VA 24502
- 4011 Highway 417, Woodruff, SC 29388

All other terms and conditions of this bond remain the same.

Signed, sealed and dated this 17th day of October, 2024

Bausch & Lomb Incorporated

Principal

Nancy J. Uksha
Witness

BY: John F. LaFave Vice President
Name: Title:

Atlantic Specialty Insurance Company

Kimberly D. Sherrod
Witness

BY: Babette Ward
Attorney-In-Fact Babette Ward

605 Highway 169 North, Suite 800
Plymouth, Minnesota, USA 55441
Web: intactspecialty.com/surety
E-mail: surety@intactinsurance.com

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Sara Owens, Wayne G. McVaugh,** each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC- MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 17th day of October 2024.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

This bond replaces and supercedes previous dated bonds written through Fidelity and Deposit Company of Maryland using Bond No. 08836635

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800140418

Application/License No. _____

BAUSCH & LOMB INCORPORATED (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Bausch & Lomb Place Rochester, NY 14604 (Address of Applicant/Principal), as PRINCIPAL, and ATLANTIC SPECIALTY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 5, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of August, 2022.

APPLICANT/PRINCIPAL
BAUSCH & LOMB INCORPORATED

COMPANY

BAUSCH & LOMB INCORPORATED CORPORATE SEAL NEW YORK

Authorized Representative/Title

SURETY
ATLANTIC SPECIALTY INSURANCE COMPANY

Sara Owens
Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness Samantha Agnoletto

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by

Nevada Resident Agent

Kimberly Sherrod; Non resident agent

Posted February 20, 2020

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Elizabeth Marrero, Wayne G. McVaugh, Sara Owens, Patricia A. Rambo, Kimberly Sherrod, George Gionis, Cathy H. Ho, Vicki Johnston, Jaquanda S. Martin, Kaidyn Malkowski**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 5th day of August 2022

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Bausch & Lomb Incorporated MDEG License # (if applicable) N/A

Physical Address 1501 Graves Mill Road

City Lynchburg State VA Zip 24502

Mailing Address (if different from physical address) 32 Discovery, Suite 200, Attn: Sharath Gadasally

City Irvine State CA Zip 92618

Telephone 434-385-0407 Website www.bausch.com

Licensing Company Email statelicensing@bausch.com

Section 2: Personal Information

First Randall Middle Ray Last Morris

Alias(es, nicknames, name changes, etc.) Randy

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State CA Zip 92618

Telephone 434-385-1746 Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Averett University			05/2000 - 12/2003	
Address		City	State	Zip
420 West Main St.		Danville	VA	24541
Diploma/Degree obtained, if any				
BBA Business				

School Name			From - To (MM/YY – MM/YY)	
WILLIAM CAMPBELL HIGH SCHOOL			08/73 - 06/77	
Address		City	State	Zip
474 WILLIAM CAMPBELL DR		GLADYS	VA	24554
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - Present	[redacted]	[redacted]	VA	24521
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Bausch & Lomb Incorporated			From - To (MM/YY – MM/YY)
Business Address: 1501 Graves Mill Road	City: Lynchburg	State: VA	Zip: 24502
Phone: 434-385-0407	Title: Distribution Center Site Lead		Number of Employed Hours: 40 hours per week
Description of Duties: Manager of Operations and Distribution Center Site Lead at the Lynchburg, VA facility.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/1992	03/1993	VA	Lynchburg	Lynchburg

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CR93004377-00	Commonwealth of VA

Reason/Charge	
ATT OBT PROP FAL PRE	

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below: FOLLOWING HAS BEEN PREVIOUSLY DISCLOSED:

In 1983, the Designated Representative, Randall "Randy" R. Morris, was charged with Failure to appear before the court. The charge was considered a misdemeanor. On March 8, 1993, he did come forward for this charge and was convicted of attempt to Obtain Property by False Pretense for using a credit card that wasn't his. This charge was considered a felony. He went through rehabilitation for alcohol dependency and since that time (approximately 30 years), his record has been clear other than minor traffic violations.

Randall R Morris

Original Signature (electronic, copies or stamps not accepted)

08-28-2024

Date

Name List | Pleadings/Orders | Main Menu | Logoff

Lynchburg Circuit - Criminal Division

Case Details

Case Number: CR93004377-00	**Filed:** 01/20/1993	**Commenced by:** Indictment	**Locality:** COMMONWEALTH OF VA
Defendant: MORRIS, RANDALL RAY	**Sex:** Male	**Race:** White	**DOB:** [redacted]
Address: BROOKNEAL, VA			
Charge: ATT OBT PROP FAL PRE	**Code Section:** 18.2-178	**Charge Type:** F	**Class:** O
Offense Date: 11/11/1992	**Arrest Date:** 11/11/1992		

Hearings

#	Date	Time	Type	Room	Plea	Duration	Jury	Result
1	02/01/1993	9:30AM	Grand Jury					True Bill
2	03/08/1993	9:30AM	Trial		Guilty			Sentenced

Final Disposition

Disposition Code: Guilty	**Disposition Date:** 03/08/1993	**Concluded By:** Guilty Plea
Amended Charge:	**Amended Code Section:**	**Amended Charge Type:**

Jail/Penitentiary: Penitentiary	**Concurrent/Consecutive:**	**Life/Death:**
Sentence Time: 2 Year(s)0 Month(s)0 Day(s)	**Sentence Suspended:** 1 Year(s)11 Month(s)0 Day(s)	**Operator License Suspension Time:**
Fine Amount:	**Costs:**	**Fines/Cost Paid:**
Program Type:	**Probation Type:**	**Probation Time:**
Probation Starts:	**Court/DMV Surrender:**	**Driver Improvement Clinic:**

Driving Restrictions:	**Restriction Effective Date:**	
VA Alcohol Safety Action:	**Restitution Paid:**	**Restitution Amount:**
Military:	**Traffic Fatality:**	

Appealed Date:

Name List | Pleadings/Orders | Main Menu | Logoff

Build #: 3.9.0.1

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

I, Randall R. Morris, **certify that as the MDEG Administrator for**

Bausch & Lomb Incorporated,

that I (initial that you have read and meet the following requirements):

1. RM Have a high school diploma or its equivalent;
2. RM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Randall R. Morris
Print Name (First, Last)

Randall R Morris
Original Signature (electronic, copies or stamps not accepted)

08-28-2024
Date

Board Use Only	Date Received: 9/25/24

Attachment F

Designated Representative Form

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bausch & Lomb Incorporated

Pharmacy/Wholesaler License # (if applicable) WH00853

Physical Address 1501 Graves Mill Road

City Lynchburg State VA Zip 24502

Mailing Address (if different from physical address) 32 Discovery, Suite 200, Attn: Sharath Gadasally

City Irvine State CA Zip 92618

Telephone 434-385-0407 Website www.bausch.com

Licensing Company Email statelicensing@bausch.com

Section 2: Personal Information

First Randall Middle Ray Last Morris

Alias(es, nicknames, name changes, etc.) Randy

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State CA Zip 92618

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Averett University		05/2000 - 12/2003	
Address	**City**	**State**	**Zip**
420 West Main St.	Danville	VA	24541
Diploma/Degree obtained, if any			
BBA Business			

School Name		From - To (MM/YY – MM/YY)	
WILLIAM CAMPBELL HIGH SCHOOL		08/73 - 06/77	
Address	**City**	**State**	**Zip**
474 WILLIAM CAMPBELL DR	GLADYS	VA	24544
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2001 - Present	[redacted]	[redacted]	VA	24521
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Bausch & Lomb Incorporated			From - To (MM/YY – MM/YY): 07/18 - Present
Business Address: 1501 Graves Mill Road	City: Lynchburg	State: VA	Zip: 24502
Phone: 434-385-0407	Title: Distribution Center Site Lead		Number of Employed Hours: 40 hours per week
Description of Duties: Manager of Operations and Distribution Center Site Lead at the Lynchburg, VA facility.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) See page 7.	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/11/1992	03/1993	VA	Lynchburg	Lynchburg
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CR93004377-00		Commonwealth of VA		
Reason/Charge				
ATT OBT PROP FAL PRE				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
		N/A		
Name of Business/Industry/Entity				
N/A				

Provide explanation below: This has been previously disclosed:

In 1983, the Designated Representative, Randall "Randy" R. Morris, was charged with Failure to appear before the court. The charge was considered a misdemeanor. On March 8, 1993, he did come forward for this charge and was convicted of attempt to Obtain Property by False Pretense for using a credit card that wasn't his. This charge was considered a felony. He went through rehabilitation for alcohol dependency and since that time (approximately 30 years), his record has been clear other than minor traffic violations.

Randall R. Morris

Original Signature (electronic, copies or stamps not accepted)

08-28-2024

Date

I, Randall R. Morris, **certify that as the designated representative for**

Bausch & Lomb Incorporated,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RM I am at least 21 years of age;
3. RM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Randall Morris

Print Name (First, Last)

R R M

Original Signature (electronic, copies or stamps not accepted)

08-28-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Randall Morris

Print Name (First, Last)

R l e l R M

Original Signature (electronic, copies or stamps not accepted)

08-28-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Virginia, ss. City County of Lynchburg

I, RANDALL MORRIS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

R l e l R M

Original Signature

08-28-2024

Date

Subscribed and Sworn to before me this 28th day of August.

Bertha E. Hicks

Notary Public Signature

BERTHA E. HICKS
NOTARY PUBLIC
REG. #7228947
MY COMMISSION EXPIRES 9/30/2024
COMMONWEALTH OF VIRGINIA
(Seal)

Name List | Pleadings/Orders | Main Menu | Logoff

Lynchburg Circuit - Criminal Division

Case Details

Case Number: CR93004377-00	**Filed:** 01/20/1993	**Commenced by:** Indictment	**Locality:** COMMONWEALTH OF VA
Defendant: MORRIS, RANDALL RAY	**Sex:** Male	**Race:** White	**DOB:** [redacted]
Address: BROOKNEAL, VA			
Charge: ATT OBT PROP FAL PRE	**Code Section:** 18.2-178	**Charge Type:** F	**Class:** O
Offense Date: 11/11/1992	**Arrest Date:** 11/11/1992		

Hearings

#	Date	Time	Type	Room	Plea	Duration	Jury	Result
1	02/01/1993	9:30AM	Grand Jury					True Bill
2	03/08/1993	9:30AM	Trial		Guilty			Sentenced

Final Disposition

Disposition Code: Guilty	**Disposition Date:** 03/08/1993	**Concluded By:** Guilty Plea
Amended Charge:	**Amended Code Section:**	**Amended Charge Type:**

Jail/Penitentiary: Penitentiary	**Concurrent/Consecutive:**	**Life/Death:**
Sentence Time: 2 Year(s)0 Month(s)0 Day(s)	**Sentence Suspended:** 1 Year(s)11 Month(s)0 Day(s)	**Operator License Suspension Time:**
Fine Amount:	**Costs:**	**Fines/Cost Paid:**
Program Type:	**Probation Type:**	**Probation Time:**
Probation Starts:	**Court/DMV Surrender:**	**Driver Improvement Clinic:**

Driving Restrictions:	**Restriction Effective Date:**	
VA Alcohol Safety Action:	**Restitution Paid:**	**Restitution Amount:**
Military:	**Traffic Fatality:**	

Appealed Date:

Name List | Pleadings/Orders | Main Menu | Logoff

Build #: 3.9.0.1

Active Employees as of 08/28/24

First Name	Last Name
William	Alexander
Richard	Alker
Kenneth	Amidei
Cletus	Ashong
Emmanuel	Ashong
Lontina	Austin
Kathy	Ballinger
Myasia	Barbour
Adam	Beach
Aurelio	Beatingo
Tamela	Bennett
Sean	Berry
Benjamin	Borah
Almith	Bowers
Cherie	Boyd
Lisa	Boyer
April	Braul
Naomi	Breakstone
Toni	Brogdon
Gena	Brooks
Kerry	Brooks
Darryl	Brown
Kaylyn	Brown
Keasia	Brown
Connie	Bryant
Torrance	Burks
Karen	Burnside
Garfield	Calloway
Olivia	Campbell
Robert	Campbell
Leon	Carter
Shantel	Carter
Ezequiel	Caruso
Jeffery	Cash
Darnel	Chambers
Dennis	Charlton
James	Cheatham
Marylene	Clark
Michelle	Clay
Elizabeth	Coffman
Eric	Coleman
Vanessa	Coleman
Erik	Cooper
Khadajia	Coward
Stacy	Crabtree
Joshua	Creasey
Juanita	Crist
Ryan	Crotser
Hilda	Cruz Lang

Tina	Cyrus
Jessica	Czaban
Rebekah	Daughtry
Joseph	Davis
Timothy	Dobiac
Patricia	Dodd
Lucas	Dongweck
Alicia	Doria
Jennifer	Duncan
Jennifer	Duncan
LeRonda	Dye
Cheryl	Elam
RaeShawn	Ellis
Deunta	Farmer
Jovita	Farnsworth
Veronica	Faulconer Woodell
Allison	Ferris
James	Fiddes
Robert	Fitzgerald
Elizabeth	Flores
Nathan	Fortney
Andrea	Franklin
Cierra	Franklin
Lamont	Franklin
Nicole	Franklin
Russell	Franklin
Valerie	Franklin
Shateria	Frink
Wendy	Gafford
Tawfik	Ghonem
Victoria	Godsoe
Janie	Guitron
Megan	Hagerty
Traci	Hall
Akeiba	Halloway
Taylor	Halsey
Cheryl	Hamilton
Cynthia	Hamlet
Yvonne	Hamlett
Tkemah	Hamm
Monica	Hardy
Allen	Harless
Marcia	Harless
Raymond	Harris
Robert	Harris
Daniel	Hartwick
Shakur	Harvey
Bertha	Hicks
Lt	Hilliard
Essence	Hood
Timeka	Horsley
Macin	Horstemeyer

Beverly	Howell
Bernice	Hudson
Katherine	Hudson
April	Hughes
Leslie	Humbles
Teira	Hunt
Hilda	Jackson
Jerome	Jackson
Sandy	Jackson
Jessica	Jacobsen
Devon	James
Yonel	Jean-Charles
Elanitia	Jefferson
Evelyn	Jefferson
Brandon	Jones
Margaret	Jones
Amber	Jordan
Ruby	King
Eric	Laughlin
John	Laughlin
James	Lawson
Grady	Lee
Stephen	Leonardo
Christopher	Lilly
John	Lindstrom
Junalyn	Lovelace
James	Lowe
Cody	MacArthur
Jamila	Makullah
Dorothea	Marshall
Gregory	Marshall
Jason	Martin
Nacori	Martin
Michael	Mason
Karen	Mawyer
Stephanie	Mayberry
Ximene	Mayberry
TyShanea	Mays
Joseph	McAdoo
Melvene	McCoy
Sarah	McCoy
Porsha	McIvor
Cierra	Megginson
David	Megginson
Sarah	Miller
Zachary	Moore
Randy	Morris
Satish	Nair
Michael	Nance
Neema	Njau
Eileen	Norman
Jonathan	O'Brien

Teresa	O'Brien
Dana	Ogden-Lewis
Russell	Olimpio
Brian	Oliver
Jovelyn	Osborne
Kelly	Overstreet
Steven	Parish
Lisa	Parker
Leticia	Parrish
Karen	Peerman
Janet	Perrow
Sheila	Peters
Megan	Phillips
Melvin	Pollard
Michelle	Preston
Vanessa	Preston
Lolanda	Price
Daniel	Putt
Rebecca	Reynolds
Jamie	Rice
William	Richards
Bria	Roberson
Jerome	Robinson
Barry	Rucker
James	Russell
Steve	Salassi
Htiek	Saunders
Kashodd	Saunders
Kelvin	Saunders
April	Sayre
Alice	Scott
Timothy	Scott
Yolanda	Scott
Cullen	Seavers
Brittney	Shankle
Ronnie	Silas
Valerie	Silas
Angelene	Smith
Elizabeth	Smith
Jalin	Smith
Larry	Smith
Timothy	Smith
Gisele	Souza
Elaine	Staten
Elizabeth	Tanner
Debra	Thomas
Kathrine	Thomas
Rhonda	Thomas
Marshall	Thompson
Melissa	Thompson
Brenda	Thornhill
Margie	Thornton

Alison	Tolley
Bennett	Tucker
Michelle	Tweedy
Alfred	Udobong
William	Wade
Betty	Ware
Raquel	Ware
Brennan	Washington
Carrie	Webb
Keyshawn	Wesley
Gerald	Wheaton
George	Williams
Russell	Wilson
Zachary	Wilson
Wayne	Wingo
Cathy	Witcher
Sherry	Woods
Shelia	Wright
Torren	Wynn
Brenda	Yaffe
Briana	Younger
Alijah	Yuille
Porsha	Yuille

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* See Attachment A ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02449	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bausch & Lomb Incorporated

Physical Address: 4011 Highway 417

City: Woodruff State: SC Zip: 29388

Mailing Address (if different from physical address): 32 Discovery, Suite 200, Attn: Sharath Gadasally

City: Irvine State: CA Zip: 92618

Telephone: 864-756-7613 Website: www.bausch.com

Name of Designated Representative (DR): Sheryal L. Sanders

Licensing Company Email: statelicensing@bausch.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Own label distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No pharmaceuticals products are sold, dispensed, or distributed by this facility.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Bausch+Lomb Netherlands B.V.

Corporation/Organization Name: Bausch & Lomb Incorporated

Mailing Address: 32 Discovery, Suite 200, Attn: Sharath Gadasally

City: Irvine State: CA Zip: 92618

Telephone: 310-936-9542 Email: statelicensing@bausch.com

Contact Person Name: Sharath Gadasally

/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bausch & Lomb Incorporated

Facility Name

Sheryal L. Sanders

Print Name of Authorized Person Submitting Application

Sheryal Sanders

Original signature of Authorized Person (copies or stamps not accepted)

9/17/2024

Date

Board Use Only	Date Received: 9/18/24	Amount: $1000-ck 1940

An official website of the United States government Here's how you know

FDA

Search Result

Share Tweet LinkedIn Email Print

Current through August 26, 2024

You have searched Finished drug products

Search Results: *'24208'*

Back to Search Page

RESET

Showing 1 to 50 of 161 entries

Show entries

Advanced Eye Relief Dry Eye Rejuvenation	24208-454-30	3mg/mL, 10 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-454	glycerin propylene glycol	GLYCERII PROPYLE GLYCOL

0453

Advanced Eye Relief Dry Eye Rejuvenation	24208-454-32	3mg/mL, 10 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-454	glycerin propylene glycol	GLYCERII PROPYLE GLYCOL
Advanced Eye Relief Eye Wash	24208-005-04	99.05mL/100mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorprated	24208-005	water solution	WATER
Advanced Eye Relief/ Redness Maximum Relief	24208-450-15	5mg/mL, .3 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-450	Naphazoline Hydrochloride and Hypromellose	HYPROMI UNSPECI NAPHAZC HYDROCI
Alaway	24208-601-05	.25mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA021996	Bausch & Lomb Incorporated	24208-601	Ketotifen Fumarate	KETOTIFE FUMARAT
Alaway	24208-601-10	.25mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA021996	Bausch & Lomb Incorporated	24208-601	Ketotifen Fumarate	KETOTIFE FUMARAT
Alaway	24208-601-90	.25mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA021996	Bausch & Lomb Incorporated	24208-601	Ketotifen Fumarate	KETOTIFE FUMARAT
Alaway Preservative Free	24208-600-01	.35mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA208158	Bausch & Lomb Incorporated	24208-600	ketotifen fumarate	KETOTIFE FUMARAT
Alaway Preservative Free	24208-600-99	.35mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA208158	Bausch & Lomb Incorporated	24208-600	ketotifen fumarate	KETOTIFE FUMARAT

0454

Alcohol Antiseptic	24208-061-01	.8mL/g	GEL	TOPICAL	part333A	Bausch & Lomb Incorporated	24208-061	alcohol	ALCOHOL
Alrex	24208-353-01	2mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	NDA020803	Bausch & Lomb Incorporated	24208-353	loteprednol etabonate	LOTEPRE ETABONA
Alrex	24208-353-05	2mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	NDA020803	Bausch & Lomb Incorporated	24208-353	loteprednol etabonate	LOTEPRE ETABONA
Alrex	24208-353-10	2mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	NDA020803	Bausch & Lomb Incorporated	24208-353	loteprednol etabonate	LOTEPRE ETABONA
Atropine Sulfate	24208-825-55	10mg/g	OINTMENT	OPHTHALMIC	N/A	Bausch & Lomb Incorporated	24208-825	Atropine Sulfate	ATROPINI SULFATE
Atropine Sulfate	24208-965-01	10mg/mL	SOLUTION	OPHTHALMIC	NDA213581	Bausch & Lomb Incorporated	24208-965	Atropine Sulfate	ATROPINI SULFATE
Bacitracin Zinc and Polymyxin B Sulfate	24208-555-55	500[USP'U]/g, 10000 [USP'U]/g	OINTMENT	OPHTHALMIC	ANDA064046	Bausch & Lomb Incorporated	24208-555	Bacitracin Zinc and Polymyxin B Sulfate	BACITRA(POLYMYX SULFATE
Bepotastine Besilate	24208-630-05	15mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA022288	Bausch & Lomb Incorporated	24208-630	bepotastine besilate	BEPOTAS BESILATE
Bepotastine Besilate	24208-630-10	15mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA022288	Bausch & Lomb	24208-630	bepotastine besilate	BEPOTAS BESILATE

0455

						Incorporated			
Bepreve	24208-629-01	15mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA022288	Bausch & Lomb Incorporated	24208-629	bepotastine besilate	BEPOTAS BESYLAT
Bepreve	24208-629-02	15mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA022288	Bausch & Lomb Incorporated	24208-629	bepotastine besilate	BEPOTAS BESYLAT
Bepreve	24208-629-03	15mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA022288	Bausch & Lomb Incorporated	24208-629	bepotastine besilate	BEPOTAS BESYLAT
Besivance	24208-446-02	6mg/mL	SUSPENSION	OPHTHALMIC	NDA022308	Bausch & Lomb Incorporated	24208-446	Besifloxacin	BESIFLO
Besivance	24208-446-05	6mg/mL	SUSPENSION	OPHTHALMIC	NDA022308	Bausch & Lomb Incorporated	24208-446	Besifloxacin	BESIFLO
Biotrue Hydration Boost	24208-006-05	5mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-006	Glycerin	GLYCERI
Biotrue Hydration Boost	24208-006-10	5mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-006	Glycerin	GLYCERI
Biotrue Hydration Boost	24208-006-11	5mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-006	Glycerin	GLYCERI

0456

Biotrue Hydration Boost	24208-006-30	5mg/mL	SOLUTION/ DROPS	OPHTHALMIC	part349	Bausch & Lomb Incorporated	24208-006	Glycerin	GLYCERI
Brimonidine Tartrate	24208-411-05	2mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA076260	Bausch & Lomb Incorporated	24208-411	Brimonidine Tartrate	BRIMONI TARTRAT
Brimonidine Tartrate	24208-411-10	2mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA076260	Bausch & Lomb Incorporated	24208-411	Brimonidine Tartrate	BRIMONI TARTRAT
Brimonidine Tartrate	24208-411-15	2mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA076260	Bausch & Lomb Incorporated	24208-411	Brimonidine Tartrate	BRIMONI TARTRAT
BRINZOLAMIDE	24208-464-10	10mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	ANDA204884	Bausch & Lomb Incorporated	24208-464	brinzolamide	BRINZOL
BRINZOLAMIDE	24208-464-15	10mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	ANDA204884	Bausch & Lomb Incorporated	24208-464	brinzolamide	BRINZOL
Cyclopentolate Hydrochloride	24208-735-01	10mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA040075	Bausch & Lomb Incorporated	24208-735	Cyclopentolate Hydrochloride	CYCLOPE HYDROCI
Cyclopentolate Hydrochloride	24208-735-06	10mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA040075	Bausch & Lomb Incorporated	24208-735	Cyclopentolate Hydrochloride	CYCLOPE HYDROCI
Desmopressin Acetate	24208-342-05	.1mg/mL	SOLUTION	NASAL	ANDA074830	Bauch & Lomb Incorporated	24208-342	Desmopressin Acetate	DESMOPI ACETATE

0457

Dexamethasone Sodium Phosphate	24208-720-02	1mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA040069	Bausch & Lomb Incorporated	24208-720	Dexamethasone Sodium Phosphate	DEXAME SODIUM PHOSPH
Diclofenac Sodium	24208-457-05	1mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA078792	Bausch & Lomb Incorporated	24208-457	Diclofenac Sodium	DICLOFE SODIUM
Diclofenac Sodium	24208-457-25	1mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA078792	Bausch & Lomb Incorporated	24208-457	Diclofenac Sodium	DICLOFE SODIUM
Dorzolamide HCl	24208-485-10	20mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA090143	Bausch & Lomb Incorporated	24208-485	Dorzolamide HCl	DORZOL HYDROC
Dorzolamide Hydrochloride and Timolol Maleate	24208-486-05	20mg/mL, 5 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA090037	Bausch & Lomb Incorporated	24208-486	Dorzolamide Hydrochloride and Timolol Maleate	DORZOL HYDROC TIMOLOL
Dorzolamide Hydrochloride and Timolol Maleate	24208-486-10	20mg/mL, 5 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA090037	Bausch & Lomb Incorporated	24208-486	Dorzolamide Hydrochloride and Timolol Maleate	DORZOL HYDROC TIMOLOL
Erythromycin	24208-910-19	5mg/g	OINTMENT	OPHTHALMIC	ANDA064067	Bausch & Lomb Incorporated	24208-910	Erythromycin	ERYTHR
Erythromycin	24208-910-55	5mg/g	OINTMENT	OPHTHALMIC	ANDA064067	Bausch & Lomb Incorporated	24208-910	Erythromycin	ERYTHR

0458

Flunisolide	24208-344-25	.25mg/mL	SOLUTION	NASAL	ANDA074805	Bausch & Lomb Incorporated	24208-344	Flunisolide	FLUNISOL
Fluorescein Sodium and Benoxinate Hydrochloride	24208-734-05	4.4mg/mL, 2.6 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA211039	Bausch & Lomb Incorporated	24208-734	Fluorescein Sodium and Benoxinate Hydrochloride	BENOXIN HYDROCI FLUORES SODIUM
Flurbiprofen Sodium	24208-314-25	.3mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA074447	Bausch & Lomb Incorporated	24208-314	Flurbiprofen Sodium	FLURBIPF SODIUM
Gentamicin Sulfate	24208-580-60	3mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA064048	Bausch & Lomb Incorporated	24208-580	Gentamicin Sulfate	GENTAMI SULFATE
Ipratropium bromide	24208-398-30	21ug/1	SPRAY, METERED	NASAL	ANDA076025	Bausch & Lomb Incorporated	24208-398	Ipratropium bromide	IPRATROI BROMIDE
Ipratropium Bromide	24208-399-15	42ug/1	SPRAY, METERED	NASAL	ANDA076103	Bausch & Lomb Incorporated	24208-399	Ipratropium Bromide	IPRATROI BROMIDE
Istalol	24208-004-01	5mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA021516	Bausch & Lomb Incorporated	24208-004	Timolol Maleate	TIMOLOL

2 3 4 Next

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Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

0460

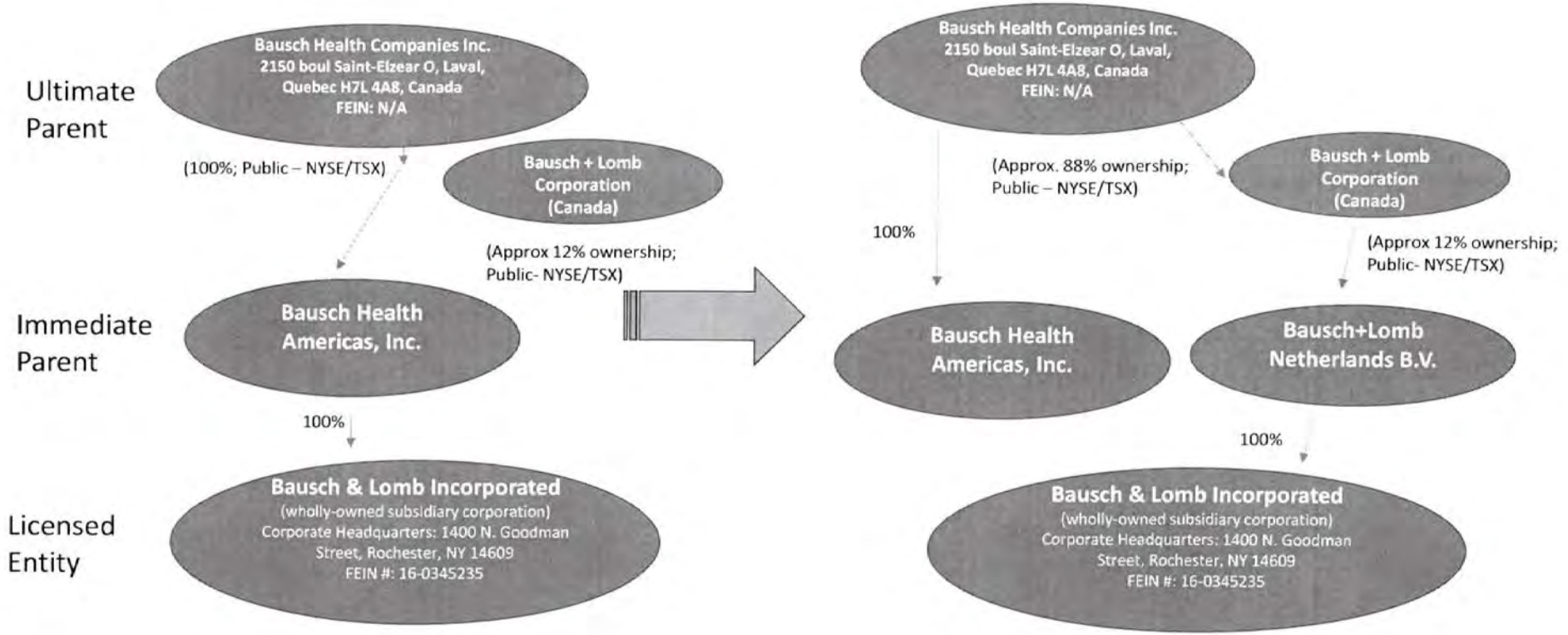
Attachment A

Regarding the Company Reorganization

Bausch & Lomb Incorporated (B&L) notifies the Board of an organizational structure change in its holding company from Bausch Health Americas, Inc. to Bausch+Lomb Netherlands B.V., a Netherlands entity, another indirect subsidiary of Bausch Health Companies Inc. Despite this change, please note that Bausch Health Companies Inc. (BHC Inc.) remains the ultimate corporate parent of B&L. Bausch Health Americas, Inc. remains an indirect subsidiary of BHC Inc. BHC Inc. remains the owner, accounting of approximately 88% of the equity interest of Bausch + Lomb Corporation.

This change results from a corporate restructure that only affects the immediate parent company of B&L while maintaining ultimate control and ownership with BHC Inc. **B&L remains a separate legal entity, with no changes in personnel or FEIN # as a result of this change.** Enclosed please find an organizational chart listing both immediate and ultimate parent and percentages of ownership/equity.

Bausch & Lomb Incorporated Organizational Change – No Change in Control



Attachment D

Corporate Officer Information

Bausch & Lomb Incorporated

Corporate Officers:

Donald A. Matheson
Vice President

John F. LaFave
Vice President

Attachment E

New York Certificate of Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	BAUSCH & LOMB INCORPORATED
DOS ID Number:	28631
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	03/20/1908
Statement Status:	CURRENT
Statement Due Date:	03/31/2024

I certify that the following is a list of documents on file in the Department of State for said entity:

Document Type:	CERTIFICATE OF INCORPORATION
Date of Filing:	03/20/1908
Entity Name:	BAUSCH & LOMB OPTICAL COMPANY
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/04/1908
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/16/1920
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	05/29/1928

Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/30/1929
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/16/1935
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/17/1937
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	12/17/1937
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	02/25/1938
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	07/16/1945
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	10/01/1945
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	10/25/1948
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/27/1949
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	01/28/1958
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	03/31/1960
Name Changed To:	BAUSCH & LOMB INCORPORATED

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 03/17/1966

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 06/03/1968

Document Type: CERTIFICATE OF MERGER
Date of Filing: 10/23/1968

Document Type: CERTIFICATE OF MERGER
Date of Filing: 11/21/1969

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/15/1970

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/12/1972

Document Type: CERTIFICATE OF MERGER
Date of Filing: 12/27/1973
Effective Date: 12/30/1973

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/03/1974

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 04/22/1976

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 04/22/1976

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/11/1979

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 09/11/1980

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 04/28/1981

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 06/27/1984

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 05/15/1985

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 09/13/1985

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 10/17/1988

Document Type: CERTIFICATE OF AMENDMENT
Date of Filing: 06/25/1992

Document Type: BIENNIAL STATEMENT
Date of Filing: 05/11/1993
Effective Date: 03/01/1993

Document Type: BIENNIAL STATEMENT
Date of Filing: 04/26/1994
Effective Date: 03/01/1994

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/20/1998
Effective Date:	03/01/1998

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/23/2000
Effective Date:	03/01/2000

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/30/2001
Effective Date:	03/31/2001

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/18/2002
Effective Date:	03/01/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/19/2002
Effective Date:	12/28/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/19/2002
Effective Date:	12/28/2002

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/09/2003
Effective Date:	12/27/2003

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/09/2003
Effective Date:	12/27/2003

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/15/2003
Effective Date:	12/27/2003

Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/30/2004
Effective Date:	03/01/2004
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	04/26/2005
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	10/11/2005
Document Type:	BIENNIAL STATEMENT
Date of Filing:	04/14/2006
Effective Date:	03/01/2006
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	10/26/2007
Document Type:	CERTIFICATE OF AMENDMENT
Date of Filing:	11/01/2007
Document Type:	BIENNIAL STATEMENT
Date of Filing:	04/23/2008
Effective Date:	03/01/2008
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	07/02/2008
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/18/2010
Effective Date:	03/01/2010
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/08/2012
Effective Date:	03/01/2012

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	07/29/2013
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/03/2014
Effective Date:	03/01/2014
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/02/2016
Effective Date:	03/01/2016
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	03/22/2018
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/28/2018
Effective Date:	03/01/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/14/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/14/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	12/17/2018
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/11/2019
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	09/06/2019
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	01/02/2020

Document Type:	CERTIFICATE OF MERGER
Date of Filing:	01/23/2020
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/19/2020
Effective Date:	03/01/2020
Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	02/08/2021
Document Type:	BIENNIAL STATEMENT
Date of Filing:	03/04/2022
Effective Date:	03/01/2022
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	03/17/2022
Document Type:	CERTIFICATE OF MERGER
Date of Filing:	06/14/2023

Above space is left blank intentionally.

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 17, 2024 at 10:48 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100005015012 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Bausch & Lomb Incorporated

4011 Highway 417
Woodruff, SC 29388

PY .22633 PWD

Wholesale/Distributor

License Expires on
06/30/2025

Archie "Artie" McKnight, II, Chair

Michael K. Bedenbaugh, Vice Chair

Effective Date
08/16/2024

Traci Collier, Board Administrator

To verify current license status, go to http://verify.llronline.com/LicLookup/LookupMain.aspx

License must be displayed publicly.

Attachment I

MDEG Administrator Form and Insurance Certificate

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/05/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA, LLC. 1166 Avenue of the Americas New York, NY 10036 030024--GAWUP-23-24	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED Bausch & Lomb Incorporated 1400 N. Goodman Street Rochester, NY 14609	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : ACE American Insurance Company — 22667 INSURER B : N/A — N/A INSURER C : N/A — N/A INSURER D : N/A — N/A INSURER E : — INSURER F : —

COVERAGES **CERTIFICATE NUMBER:** NYC-012038034-02 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDOG48898646	11/01/2023	11/01/2024	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ EXCLUDED
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	$
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of insurance for Bausch & Lomb Incorporated and its facilities, including but not limited to:
4011 Highway 417, Woodruff, SC 29388
1501 Graves Mill Road, Lynchburg, VA 24502
8500 Hidden River Pkwy, Tampa, FL 33637

CERTIFICATE HOLDER

Bausch & Lomb Incorporated d/b/a
Bausch & Lomb Americas, Inc
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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intact surety

CHANGE RIDER

To be attached to and form a part of Pharmaceutical Wholesaler Surety Bond

Bond No. 800140418 issued by **ATLANTIC SPECIALTY INSURANCE COMPANY**, 605 Highway 169 North, Suite 800, Plymouth, Minnesota, USA 55441 as Surety on behalf of Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604, as Principal in favor of State of Nevada and the Nevada State Board of Pharmacy with reference to Nevada Revised Statutes (NRS) 639.515 effective the 5th of August, 2022.

It is hereby understood and agreed that the following item is amended:

The addresses of the Principal doing or intending to do business as a pharmaceutical wholesaler, for purposes of services is amended to include the following sites:

- 1501 Graves Mill Road, Lynchburg, VA 24502
- 4011 Highway 417, Woodruff, SC 29388

All other terms and conditions of this bond remain the same.

Signed, sealed and dated this 17th day of October, 2024

Bausch & Lomb Incorporated

Principal

Nancy J. Uksha
Witness

BY: John F. LeFave Vice President
Name: Title:

Atlantic Specialty Insurance Company

Kimberly M. Sherrod
Witness

BY: Babette Ward
Attorney-In-Fact Babette Ward

605 Highway 169 North, Suite 800
Plymouth, Minnesota, USA 55441
Web: intactspecialty.com/surety
E-mail: surety@intactinsurance.com

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Sara Owens, Wayne G. McVaugh,** each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC- MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 17th day of October 2024.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2025

Please direct bond verifications to surety@intactinsurance.com

This bond replaces and supercedes previous dated bonds written through Fidelity and Deposit Company of Maryland using Bond No. 08836635

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800140418

Application/License No. _____

BAUSCH & LOMB INCORPORATED (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Bausch & Lomb Place Rochester, NY 14604 (Address of Applicant/Principal), as PRINCIPAL, and ATLANTIC SPECIALTY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 5, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of August, 2022.

APPLICANT/PRINCIPAL
BAUSCH & LOMB INCORPORATED

COMPANY

BAUSCH & LOMB INCORPORATED CORPORATE SEAL NEW YORK

Authorized Representative/DOB

SURETY
ATLANTIC SPECIALTY INSURANCE COMPANY

Sara Owens
Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness Samantha Agnoletto

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by

Nevada Resident Agent

Kimberly Sherrod; Non resident agent

Posted February 20, 2020

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Elizabeth Marrero, Wayne G. McVaugh, Sara Owens, Patricia A. Rambo, Kimberly Sherrod, George Gionis, Cathy H. Ho, Vicki Johnston, Jaquanda S. Martin, Kaitlyn Malkowski**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 5th day of August 2022

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Bausch & Lomb Incorporated MDEG License # (if applicable) N/A

Physical Address 4011 Highway 417

City Woodruff State SC Zip 29388

Mailing Address (if different from physical address) 32 Discovery, Suite 200, Attn: Sharath Gadasally

City Irvine State CA Zip 92618

Telephone 864-756-7613 Website www.bausch.com

Licensing Company Email statelicensing@bausch.com

Section 2: Personal Information

First Sheryal Middle Love Last Sanders

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State CA Zip 92618

Telephone 864-549-3126 Email sheryal.sanders@bausch.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Southern Wesleyan University		09/2002 - 05/2004	
Address	**City**	**State**	**Zip**
907 Wesleyan Dr	Central	SC	29630
Diploma/Degree obtained, if any			
Bachelor of Science – Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Greenville Technical College		09/1978 - 05/1981	
Address	**City**	**State**	**Zip**
506 S Pleasantburg Dr	Greenville	SC	29607
Diploma/Degree obtained, if any			
Associates Business Administration			

School Name		From - To (MM/YY – MM/YY)	
York Comprehensive High School		08/1973 - 05/1976	
Address	**City**	**State**	**Zip**
275 Alexander Love Highway	Love	SC	29745
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2000 - Present	[redacted]	[redacted]	SC	29669
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Bausch & Lomb Incorporated		06/1989 - Present	
Business Address	**City**	**State**	**Zip**
4011 Highway 417	Woodruff	SC	29388
Phone	**Title**	**Number of Employed Hours**	
864-756-7613	Manager, Distribution	40 hours per week	

Description of Duties
Site Lead - Oversight of WDC Operations- direct reports; three Supervisors and Inventory Control. Management of 3PL for international storage and distribution. Experienced Supply Chain Professional with expertise in warehouse operations, distribution, international and domestic transportation. More than 30 years of demonstrated ability to understand and meet customer requirements in support of aggressive sales goals. Management of projects for cost savings and improved efficiencies. Extensive knowledge of the entire Distribution Operation.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below: N/A

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Sheryal L. Sanders, **certify that as the MDEG Administrator for**

Bausch & Lomb Incorporated,

that I (initial that you have read and meet the following requirements):

1. SS Have a high school diploma or its equivalent;
2. SS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheryal Sanders
Print Name (First, Last)

Sheryal Sanders
Original Signature (electronic, copies or stamps not accepted)

9/06/2024
Date

Board Use Only	Date Received: 9/25/24

Attachment F

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bausch & Lomb Incorporated

Pharmacy/Wholesaler License # (if applicable) WH02449

Physical Address 4011 Highway 417

City Woodruff State SC Zip 29388

Mailing Address (if different from physical address) 32 Discovery, Suite 200, Attn: Sharath Gadasally

City Irvine State CA Zip 92618

Telephone 864-756-7613 Website www.bausch.com

Licensing Company Email statelicensing@bausch.com

Section 2: Personal Information

First Sheryal Middle Love Last Sanders

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI[redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State CA Zip 92618

Telephone [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Southern Wesleyan University		09/2002 - 05/2004	
Address	**City**	**State**	**Zip**
907 Wesleyan Dr	Central	SC	29630
Diploma/Degree obtained, if any			
Bachelor of Science – Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Greenville Technical College		09/1978 - 05/1981	
Address	**City**	**State**	**Zip**
506 S Pleasantburg Dr	Greenville	SC	29607
Diploma/Degree obtained, if any			
Associates Business Administration			

School Name		From - To (MM/YY – MM/YY)	
York Comprehensive High School		08/1973 - 05/1976	
Address	**City**	**State**	**Zip**
275 Alexander Love Highway	Love	SC	29745
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2000 - Present	[redacted]	[redacted]	SC	29669
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bausch & Lomb Incorporated			06/1989 - Present	
Business Address		**City**	**State**	**Zip**
4011 Highway 417		Woodruff	SC	29388
Phone	**Title**		**Number of Employed Hours**	
864-756-7613	Manager, Distribution		40 hours a week	

Description of Duties

Site Lead - Oversight of WDC Operations- direct reports; three Supervisors and Inventory Control. Management of 3PL for international storage and distribution. Experienced Supply Chain Professional with expertise in warehouse operations, distribution, international and domestic transportation. More than 30 years of demonstrated ability to understand and meet customer requirements in support of aggressive sales goals. Management of projects for cost savings and improved efficiencies. Extensive knowledge of the entire Distribution Operation.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Sheryal L. Sanders, **certify that as the designated representative for**

Bausch & Lomb Incorporated,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SS I am at least 21 years of age;
3. SS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sheryal L. Sanders

Print Name (First, Last)

Sheryal L. Sanders

Original Signature (electronic, copies or stamps not accepted)

9/06/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheryal L. Sanders

Print Name (First, Last)

Sheryal L. Sanders — 9/06/24

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Spartanburg

I, Sheryal L Sanders, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sheryal L. Sanders — 9/06/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 6th day of September 2024.

Dara Monique Sanders

Notary Public Signature

DARA MONIQUE SANDERS
Notary Public, State of South Carolina
My Commission Expires 3/25/2029

(Seal)

Full Name
Aguilar, Leticia
Alewine, Jason
Alewine, Tammy
Allen, William
Allis, Zachariah
Barrett, Roberta
Bates, Darrell
Bearden, Bobby
Bennett, Alessandra
Bobo, Andre
Bouillon, Gregory
Bray, Jon
Brian, Corinthian
Brown, Jerry
Brown, Michael
Brown, Stacey
Brown, Wanda
Burriss, Nicholas
Calamia, Joseph
Case, Charles
Clark, Larry
Clements, Gail
Cohen, George
Davenport, Amber
Delvaux, Cameron
Dodson, Timothy
Donald, Roger
Douglas, William
Everett, Chaz
Floyd, Dianna
Fowler, Fredricus
Givens, Jean
Gladden, Deraymus
Goringer, Leah
Harley, Johnny
Hawkins, Jeffery
Henry, Richard
Hicks, Royal
Hiott, William
Humphries, Donald
Hunt, Shulanda
Jimenez, Yesenia
Johnson, Alison
Johnson, David
Lancaster, Thomas

Lee, Gary
Lindsey, John
Locke, Lizbeth
Massey, Antavia
Mathis, Tracy
McMorris, Treandra
Mills, Michael
Mills, Timothy
Moon, Tarnisha
Newby, Shannon
Njinimbam, Lovalla
Paperiella, Leah
Peterson, Scott
Robinson, Shawn
Ross, Kenneth
Russell, Briann
Sanchez, Salvador
Sanders, sheryal
Savoy, Quanisha
Sloan, Kimberly
Smith, Drake
Smith, Tony
Souriyasak, Solomon
Speach, Jeshua
Staton, John
Stratton, Jennifer
Suber, Kevin
Swenson, Dylan
Tate, William
Thompson, David
Vaughn, Amelia
Weppner, William
Whitman, Adam
Williams, Bobby
Williams, Gerald
Wood, Jerry
Worthy, India

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Boehringer Ingelheim Pharmaceuticals, Inc

Physical Address: 900 Ridgebury Rd.,Administrative Office Building

City: Ridgefield State: CT Zip: 06877

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (203) 798-9988 Website: www.boehringer-ingelheim.com

Name of Designated Representative (DR): Scott Segnere

Licensing Company Email: [redacted] DR Email: boehringeringelheim@iqvia.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Rx Human Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Chain Retail Pharmacie		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: UPS Supply Chain Solutions, Inc.
Address: 700 Manor Park Drive Suite#310 City: Columbus State: OH Zip: 43228
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Boehringer Ingelheim USA Corporation
Corporation/Organization Name: Boehringer Ingelheim Pharmaceuticals, Inc
Mailing Address: 900 Ridgebury Rd.,Administrative Office Building
City: Maddison State: CT Zip: 06877
Telephone: (203) 798-9988 Email: [redacted]
Contact Person Name: Scott Segnere

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Boehringer Ingelheim Pharmaceuticals, Inc

Facility Name

Christian Orth

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/27/2024

Date

Board Use Only	Date Received: _____	Amount: _____

An official website of the United States government Here's how you know

FDA

Verified Labeler 10/16/24

Search Result

Share Tweet Linkedin Email Print

Current through June 14, 2024

You have searched Finished drug products

Search Results: *'0597'*

Back to Search Page

Keyword Search RESET

Showing 1 to 146 of 146 entries (filtered from 161 total entries) Show 10 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC
Adalimumab-adbm	0597-0545-22	N/A	KIT	N/A	BLA761058	Boehringer Ingelheim Pharmaceuticals, Inc.	0597-0545
Adalimumab-adbm	0597-0545-44	N/A	KIT	N/A	BLA761058	Boehringer Ingelheim Pharmaceuticals, Inc.	0597-0545

Boehringer Ingelheim Pharmaceuticals, Inc.

900 Ridgebury Road
Ridgefield, Connecticut
FEIN: 13-2686668
Incorporated in the State of Delaware on 03/02/1971

Timmo Rousku Andersen — **President**

Business Address: 900 Ridgebury Road, Ridgefield, CT 06877
Business Phone: 203-778-7371
Home Address: [redacted] CT 06877
Home Phone: [redacted]
Ownership: 0%
Date of Birth: [redacted]
Place of Birth: [redacted]
Driver's License: [redacted]

Debra Christenson Forster — **Esq. – SVP, General Counsel & Secretary**

Business Address: 900 Ridgebury Road, Ridgefield, CT 06877
Business Phone: 203-798-4633
Home Address: [redacted] T 06877
Home Phone: [redacted]
Ownership: [redacted]
Date of Birth: [redacted]
Place of Birth: [redacted]
Driver's License: [redacted]

Christian Orth — **SVP & Chief Financial Officer**

Business Address: 900 Ridgebury Road, Ridgefield, CT 06877
Business Phone: 203-791-6580
Home Address: [redacted] CT 06810
Home Phone: N/A
Ownership: 0%
Date of Birth: [redacted]
Place of Birth: [redacted]
Driver's License: [redacted]

Corporate Officer Information

Bruce Henry Vagts, Jr. — **Assistant Treasurer**

Business Address: 900 Ridgebury Road, Ridgefield, CT 06877
Business Phone: 203-791-6501
Home Address: [redacted] CT 06410
Home Phone: [redacted]
Ownership: 0%
Date of Birth: [redacted]
Place of Birth:
Driver's License:

Paula Kathleen Wittmayer — **Assistant Secretary**

Business Address: 900 Ridgebury Road, Ridgefield, CT 06877
Business Phone: 203-791-6692
Home Address: [redacted] NY 10560
Home Phone:
Ownership: 0%
Date of Birth: [redacted]
Place of Birth:
Driver's License:

VIRTUAL MANUFACTURER STATEMENT

Boehringer Ingelheim Pharmaceuticals, Inc. is a virtual manufacturer of prescription drugs and OTC products and, therefore, does not handle prescription drugs and OTC products at any time either for physical manufacturing or distribution. However, they do maintain product ownership and are responsible for the oversight and sale of product.

Pursuant to 21CFR 1301.11 Boehringer Ingelheim Pharmaceuticals, Inc. does not propose to engage in the manufacture, distribution, importation, or exportation of controlled substances or prescription drugs and, therefore, is exempt from federal registration.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BOEHRINGER INGELHEIM PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





770518 8300

SR# 20241815622

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203386027

Date: 05-02-24

CTL-03 Rev. 06/13

1041295

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information with our office current to receive correspondence. All renewal notifications and certificates will only be emailed to your last reported email on record. You can update your email, mailing address or print a duplicate certificate by logging into your account with your User ID and Password at www.elicense.ct.gov. Visit our website at www.ct.gov/dcp.

Mailing address:

BOEHRINGER INGELHEIM PHARMACEUTICALS INC
900 RIDGEBURY RD
ADMINISTRATIVE OFFICE BUILDING
RIDGEFIELD, CT 06877-1058

Email on file to be used for receiving all notices from this office:

boehringeringelheim@iqvia.com

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION 1041295

Be it known that

BOEHRINGER INGELHEIM PHARMACEUTICALS INC
900 RIDGEBURY RD
ADMINISTRATIVE OFFICE BUILDING
RIDGEFIELD, CT 06877-1058

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No Rx Legend Drugs: Yes Non Rx Legend Drugs: Yes Medical Devices: No Cosmetics: No
Medical Gases and Oxygen: No Durable Medical Equipment (DME): No Number of Chemists: 0

Registration #: CSM.0002702
Effective Date: 07/26/2024
Expiration Date: 06/30/2025

verify online at www.elicense.ct.gov

Bryan T. Cafferelli, Commissioner

CompanyName -Boehringer Ingelheim Pharmaceuticals, Inc. - Ridgebury

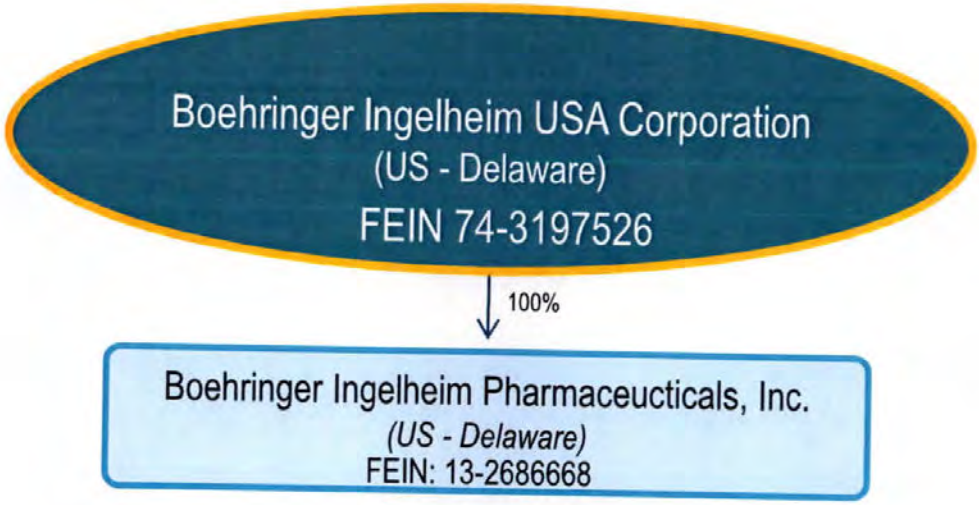
LicenseNo	TypeName	StateCode	ExpirationDate
195113	Out-of-State Wholesale Drug	AK	6/30/2024
193338	Private Label Distributor Virtu	AL	12/31/2024
DR0669	Designated Rep	AL	12/31/2024
WD03228	Wholesale Distributor of Pres	AR	12/31/2024
W002024	Non-Resident Wholesaler	AZ	10/31/2024
OSD 4886	Non-Resident Wholesaler	CA	6/1/2024
EXC 20910	Designated Rep	CA	12/1/2024
Initial App-0012	Designated Rep	CA	9/9/9999
CSM.0002702	Manufacturer	CT	9/9/2099
Initial App-0006	Wholesale Drug Distributor	DC	9/9/2099
40338	Complimentary Drug Distribut	FL	4/30/2024
262366	Non-Resident Prescription Dru	FL	5/31/2026
PHWH002312	Drug Wholesaler	GA	6/30/2025
40792	Virtual Manufacturer	IA	12/31/2024
M69704	Virtual Manufacturer	ID	12/31/2024
15-121969	Sample Distributor	KS	6/30/2025
4-122224	Virtual Manufacturer	KS	6/30/2024
00039-D	Product Registration	LA	6/30/2024
9038	Virtual Manufacturer	LA	12/31/2024
D02008	Distributor	MD	5/31/2025
Initial App-0003	Virtual Manufacturer	MI	9/9/2099
460191	Drug Manufacturer	MN	5/31/2025
Initial App-0010	Drug Distributor	MO	9/9/2099
16334/16.4AM	Virtual Manufacturer	MS	12/31/2024
PHA-WDD-LIC-3147	Wholesale Distributor	MT	11/30/2024
382	Virtual Manufacturer	NC	12/31/2024
Whol3104	Wholesale Drug Mfg/Dist	ND	6/30/2025
07967	Manufacturer/Wholesaler/Dis	NH	1/31/2025
5003344	Drug or Medical Device Whole	NJ	1/31/2025
WD20220151	Wholesale Drug Distributor	NM	12/31/2025
Initial App-0007	Wholesaler	NV	9/9/2099
011599850	Wholesaler Virtual	OH	6/30/2025
88-M-1660	Manufacturer	OK	8/31/2024
M-0001679	Manufacturer	OR	9/30/2024
1000004454	Distributor	PA	2/28/2025
21722	Non-Resident Virtual Manufac	SC	6/30/2025
600-1206	Wholesaler	SD	12/31/2024
Initial App-0005	Manufacturer	TN	9/9/2099
0090323	Out-of-State Drug Distributor	TX	6/4/2026
13716410-1710	Pharmacy Class C Manufactur	UT	9/30/2025
163.0000476	Non-Resident Manufacturer	VT	7/31/2025
PHWH.FX.60064751	Pharmaceutical Wholesaler	WA	9/30/2024
DRSD.FX.00058855	Drug Sample Distributor Regis	WA	9/30/2024
MR0552536	Manufacturer	WV	6/30/2026
WD2371	Manufacturer/Distributor	WY	6/30/2025

Boehringer Ingelheim Pharmaceuticals, Inc.
Ownership Org Chart

Boehringer Ingelheim

Confidential

New Org Chart



This legal entity ownership structure will become effective **December 1, 2023**, after Boehringer Ingelheim Corporation merges into Boehringer Pharmaceuticals, Inc. on November 30, 2023.

This Bond Replaces and Supersedes Travelers ualty and Surety Company of America Bond N r 106397706 dated October 26th, 2015

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K09596392

Application/License No. _____

Boehringer Ingelheim Pharmaceuticals, Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 900 Ridgebury Road, Ridgefield, CT 06877 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 436 Walnut Street, Philadelphia, PA 19106-3703 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 26, 2017 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of August, 2017.

APPLICANT/PRINCIPAL

Boehringer Ingelheim Pharmaceuticals, Inc

Authorized Representative

CHRISTIAN ARTH
VP + CFO

8/10/17

SIGNED and SEALED in the presence of:

8/30/17

Witness LEN RICHARDS

8/30/17

Witness PAMELA A. AUSTINO

SURETY COMPANY

Westchester Fire Insurance Company

Surety Company's Representative

Jessica Iannotta, Attorney-in-fact
print name
NV Non Resident Producer, License Number 3155198

SIGNED and SEALED in the presence of:

Witness April Perez

Witness Leanne Lynskey

Countersigned by

N/A

Nevada Resident Agent

N/a

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY,** a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment")

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments

(4) Each of the Chairman, the President and Vice Presidents of the Company in hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested

Does hereby nominate, constitute and appoint Annette Leuschner, April D Perez, James P Holland, Jessica Iannotta, Kelly O'Malley, Kristin S Bender, Marisol Mojica, Theresa Giraldo, all of the City of MORRISTOWN, New Jersey, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding Seventy Five million dollars & zero cents ($75,000,000 00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office.

IN WITNESS WHEREOF, the said Stephen M Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY** this 10 day of May 2016.

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M Haney, Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss

On this 10 day of May, AD 2016 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M Haney, Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company, that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Philadelphia the day and year first above written

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 26, 2018

Notary Public

I, the undersigned Assistant Secretary of the **WESTCHESTER FIRE INSURANCE COMPANY,** do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 22nd day of August, 2017.

William L. Kelly, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER May 09, 2018

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border

WESTCHESTER FIRE INSURANCE COMPANY

FINANCIAL STATEMENT **DECEMBER 31, 2016**

ADMITTED ASSETS

BONDS	$1,492,813,519
SHORT - TERM INVESTMENTS	34,890,369
STOCKS	450,903
REAL ESTATE	0
CASH ON HAND AND IN BANK	19,880,440
PREMIUM IN COURSE OF COLLECTION*	69,254,246
INTEREST ACCRUED	14,505,011
OTHER ASSETS	132,649,982
TOTAL ASSETS	$1,764,444,470

LIABILITIES

RESERVE FOR UNEARNED PREMIUMS	$200,260,562
RESERVE FOR LOSSES	851,003,190
RESERVE FOR TAXES	16,081,016
FUNDS HELD UNDER REINSURANCE TREATIES	5,666,051
OTHER LIABILITIES	(11,412,992)
TOTAL LIABILITIES	1,061,597,827
CAPITAL: 70,000 SHARES, $71.43 PAR VALUE	5,000,100
CAPITAL: PAID IN	304,543,059
AGGREGATE WRITE-INS FOR SPECIAL SURPLUS FUNDS	113,661,643
SURPLUS (UNASSIGNED)	279,641,841
SURPLUS TO POLICYHOLDERS	702,846,643
TOTAL	$1,764,444,470

(*EXCLUDES PREMIUM MORE THAN 90 DAYS DUE.)

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2016.

Sworn before me this March 22, 2017

Senior Vice President

Notary Public

August 8, 2019
My commission expires

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Diane Wright, Notary Public
City of Philadelphia, Philadelphia County
My Commission Expires Aug. 8, 2019
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Boehringer Ingelheim Pharmaceuticals, Inc

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 900 Ridgebury Rd.,Administrative Office Building

City: Ridgefield State: CT Zip: 06877

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (203) 798-9988 Website: www.boehringer-ingelheim.com

Licensing Company Email: manuela.monteiro@boehringer-ingelheim.com

Section 2: Personal Information

First: Scott Middle: D Last: Segnere

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address:

City: State: CT Zip:

Telephone: [redacted] Email: boehringeringelheim@iqvia.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pottsgrove High School		Sept 1983 - June 1987	
Address	**City**	**State**	**Zip**
1345 Kauffman Rd	Pottstown,	PA	19464
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		Aug 1987 - Dec 1992	
Address	**City**	**State**	**Zip**
4200 Fifth Ave, Pittsburgh, PA	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1998 - Present	[redacted]	[redacted]	CT	06443
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YMM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/Y – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Boehringer Ingelheim Pharmaceuticals, Inc.			2020 - Present	
Business Address		**City**	**State**	**Zip**
900 Ridgebury Rd.,Administrative Office Building		Ridgefield	CT	06877
Phone	**Title**		**Number of Employed Hours**	
+1 (203) 798-4780	Executive Director, Trade and Specialty Distribution		8K	
Description of Duties				
Provides strategic direction, options, tactics and programs for trade and channel customer (wholesaler, specialty pharmacy, retail pharmacy, long term care"LTC", group purchasing organizations "GPO", specialty distributors) to help ac				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Scott D. Segnere

[redacted] CT 06443
(E-mail) [redacted]

Experience

Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT
Human Pharma, Value & Access

May 2020 to Present

Executive Director, Trade & Specialty Distribution

- Provides strategic direction, options, tactics and programs for trade and channel customer (wholesaler, specialty pharmacy, retail pharmacy, long term care "LTC", group purchasing organizations "GPO", specialty distributors) to help achieve company objectives
- Optimize distribution; pricing and contracting strategy; and gain appropriate approvals for implementation across all channels of responsibility
- Sets distribution strategy and direct all supply chain distribution activities to achieve sales goals established by the organization
- Lead sales to and relationship management of all trade pharmacy customers for Boehringer Therapeutic Areas
- Ensure oversight of all National Accounts, Trade Operations, and Trade Strategy and Contracting
- Effectively develop and negotiate contracts with wholesalers and specialty pharmacy/distribution partners to achieve desired performance

Executive Director (Interim), Business Innovation

Aug 2019 to May 2020

- Interim responsibility to lead the Business Innovation team that includes the Digital Health function and the Strategic Customer Collaborations for Anthem and Humana
- Responsible for day-to-day team management and priority and goal setting

Sep 2018 to Aug 2019

Director, Strategic Customer Collaborations

- Accountable for leading the execution of the current strategic collaboration between BIPI, Anthem and HealthCore
- Primary focus is to drive multi-stakeholder engagement that drives a portfolio of projects that intended to inform our development and commercialization efforts
- Responsibilities include overall strategic relationship management, governance, opportunity evaluation and project portfolio management
- Additional responsibilities to support the development of new collaborations

Sep 2013 to Sep 2018

Human Pharma, Commercial Operations, Program Management Office
Executive Director

- Overall responsibility for managing a department of six continuous process improvement and program management professionals who lead a portfolio of strategic cross-functional initiatives on behalf of BIPI's Human Pharma business
- Overall PMO lead for several organizational transformation initiatives
- Champion for continuous improvement initiatives within the Human Pharma business intended to drive consistent, measurable and reproducible results for key business processes

Sep 2009 to Sep 2013

Director

- Acting PMO Department Lead
  - Responsible for PMO vision and methodology development including, development of a flexible staffing model for Prescription Medicines project management resources, concept and implementation of the Commercial Operations project and process roadmap and leading the standardization of project management tools, process and templates
  - Additional responsibilities included; acting as the primary PMO liaison for other BI departments, assisting other departments in obtaining suitable external project management resources, PMO cost center budgeting and management; and assisting in the creation of a project management training curriculum for Field Sales Management
- Overall project management lead for the BI Customer Focused Selling initiative
- Lead for the Contracting work stream of the HCP engagement initiative.
- Overall BI responsibility for all aspects of the Program Management effort for the BI/Eli Lilly Diabetes Alliance
- Overall responsibility for the initial phase of BI's commercial model redesign focused on Regional Business Planning (RBP)
- Developed and managed the process for Pradaxa Field Based Launch Readiness Planning

Apr 2009 to Sep 20009

Innovation Development

Associate Director

- Participated in the initial Phase I launch of the Geographic Business Leadership (GBL) initiative.
- Responsibilities include development of the initial Phase I timelines, estimated budget, and participation in the overall project management effort.
- Responsibility for the implementation and management of Boehringer Ingelheim's innovation Challenges (Aggrenox and 3rd Quarter Prescription Medicines Challenge)

Business IS Consulting

Feb 2007 to Apr 2009

Associate Director

- Directed all project related work to enhance and maintain Boehringer Ingelheim's CRM environment.
- Responsibilities included capital budgeting, staffing, scope and budget management and issue and change management.
- Managed multiple releases for both the sales force automation system as well as the field sales analytics environment.
- These releases successfully improved the data quality, functionality, and user experience for each of these respective applications.

C3i, Inc.

Professional Services Group, Morristown, NJ

Apr 2005 to Feb 2007

Director, Professional Services Operations

- Directed the day-to-day operations of C3i's Professional Services group with an international staff of 45. Responsible for all operational processes including resource allocation and staffing, time reporting/client billing, expense reporting and developmental/readiness and training for all Professional Services staff.

Jun 2004 to Apr 2005

Analytics Project Manager

- Primary responsibilities included project planning and execution, preparing and maintaining project schedule and budget. Acted as the primary liaison and point of contact for the customer.

Jul 2002 to Jun 2004

Analytical Business Lead/ Sr. Analytics Business Analyst

- Primary responsibilities included the facilitation and documentation of JAD sessions, development of all functional deliverables including, business/ functional requirements, analysis of current processes and reporting, and design of new reports.

Bayer Corporation, Pharmaceutical Division

Sales Systems Operations & Planning, West Haven, CT

Sep 2000 to Jan 2001

Manager, Sales Force Automation

- Managed the daily operations of the Sales Force Automation Department with a staff of nine and annual operational budget and assets of approximately $8M. Primarily responsible for the development, implementation and support of all field sales automation hardware and software including laptop computers, servers and printers among the 1800 various pharmaceutical sales representatives and management.

Sep 1998 to Sep 2000

Manager, Sales Systems Planning and Project Management

- Primary responsibilities included business process reengineering, and project management for most large-scale business system solutions for the Field Sales Force and Sales Operations Department. Additional responsibilities for strategic systems planning to support division objectives and the supervision of the project management responsibilities of two other project managers.

Sep 1997 to Aug 1998

KPMG Peat Marwick

KPMG Consulting - Customer Relationship Mgt. Practice, Stamford, CT

Consultant

- Evaluated and documented business processes for a manufacturing company in preparation for the implementation of Siebel Sales Enterprise. This project consisted of the assessment and documentation of "as-is" and "to-be" processes. Identification of bottlenecks and recommendations for streamlining the order entry process with the use of the Siebel Call Center application.
- Participated in the Sales Administration re-engineering project for a major pharmaceutical company to assess and redesign their monthly field sales and incentive compensation reporting processes. The project involved analyzing the existing processes and tools, identifying gaps and opportunities for improvement, and developing "quick strike" and long-term recommendations.

Feb 1993 to Aug 1997

Dun & Bradstreet Corporation

Technical Customer Support, Bethlehem, PA

- ***Senior Technical Support Coordinator***
- ***Technical Support Consultant***

Information Resources, Lancaster, PA

- ***Business Analyst***

Education

University of Pittsburgh, Pittsburgh, PA

- BA, Economics (Apr 1992)

Additional Training

Duke University Corporate Education
- Graduate BI Regional Leadership Development (Aug 2012)

Center for Creative Leadership
- Graduate BI Leadership Development Program (May 2009)

International Institute for Learning, Inc.
- Project Management Certificate Program (May 2008)

Digital Consulting, Inc.
- Business Rule Driven Requirements Gathering (Mar 2003)

American Management Association

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/27/2024
Date

I, Scott D Segnere, **certify that as the designated representative for**

Boehringer Ingelheim Pharmaceuticals, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SS I am at least 21 years of age;
3. SS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SCOTT SEGNERE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/27/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SCOTT SEGNERE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Connecticut, ss. County of Fairfield

I, Scott D. Segnere, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/27/2024

Date

Subscribed and Sworn to before me this 27th day of August.

Notary Public Signature

PATRICIA THOMPSON
NOTARY PUBLIC
MY COMMISSION EXPIRES 4/30/2025

(Seal)

Boehringer Ingelheim Pharmaceuticals, Inc.

900 Ridgebury Road
Ridgefield, Connecticut
FEIN: 13-2686668
Incorporated in the State of Delaware on 03/02/1971

Corporate Ownership Information

Owner/ Parent: Boehringer Ingelheim USA Corporation
FEIN: 74-3197526
Ownership: 100%
Business Address: 900 Ridgebury Rd, Ridgefield, CT 09877

List of Employee

Timmo Andersen	**President**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-448-8822
Ownership:	0%
Debra Forster	**Esq. – SVP, General Counsel & Secretary**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-798-5515
Ownership:	0%
Christian Orth	**SVP & Chief Financial Officer**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-791-6580
Ownership:	0%
Bruce Henry Vagts, Jr.	**Assistant Treasurer**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-791-6501
Ownership:	0%
Paula Kathleen Wittmayer	**Assistant Secretary**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-791-6692
Ownership:	0%
Scott D Segnere	**Executive Director, Trade and Specialty Distribution**
Business Address:	900 Ridgebury Road, Ridgefield, CT 06877
Business Phone:	203-791-6692
Ownership:	0%

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* ☑ Name Change* ☐ Location Change* (in-state only)	See Attachment A * If making a change, provide current license number: WH 01623	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bora Pharmaceuticals Injectables Inc.

Physical Address: 1111 South Paca Street

City: Baltimore State: MD Zip: 21230

Mailing Address (if different from physical address): 1111 South Paca Street, Attn: Quality Systems – Client Support

City: Baltimore State: MD Zip: 21230

Telephone: 410-843-5000 Website: https://bora-corp.com/

Name of Designated Representative (DR): David Fidler

Licensing Company Email: qsauditcompliance@bora-corp.com DR Email: qsauditcompliance@bora-corp.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Bora Pharmaceuticals USA Inc.

Corporation/Organization Name: Bora Pharmaceuticals Injectables Inc.

Mailing Address: 1111 South Paca Street

City: Baltimore State: MD Zip: 21230

Telephone: 410-843-5000 Email: 410-843-4414

Contact Person Name: David Fidler

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: N/A		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment A	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment A	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bora Pharmaceuticals Injectables Inc.

Facility Name

David Fidler

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

30 AUG 2024

Date

Board Use Only	Date Received: 9/5/24	Amount: $1,000 Ck #115

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov Menu

Home Drug Databases DECRS Search Result

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Drug Establishments Current Registration Site

New Search

Search Results for *Bora*

Showing 1 to 1 of 1 entries (filtered from 528 total entries) Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Bora Pharmaceuticals Injectables Inc.	1000512361	119352788	ANALYSIS; LABEL; MANUFACTURE; PACK	1111 S Paca St, Baltimore, Maryland (MD) 21230, United States (USA)	12/31/2024

Previous 1 Next

Data Current Through: Thursday, Sep 26, 2024

New Search

Attachment A

Regarding the Changes and Resident State License

On August 20, 2024, Bora Pharmaceuticals Injectables Inc. purchased Cangene bioPharma LLC's Baltimore, MD facility through an asset purchase agreement. The facility will conduct business under Bora Pharmaceuticals Injectables Inc. There are no changes to personnel or management at the facility. Provided below are the corporate officers for Bora Pharmaceuticals Injectables Inc. Legal documentation of the ownership change will be provided when available. Please note that the updated resident state license is pending with the Maryland Board of Pharmacy. Once received, a copy of the updated license will be provided.

Corporate Officers:

Pao-Shi Sheng
Chairman/CEO
Business address: 1111 S. Paca St., Baltimore, MD 21230

Hsiaoting Chen
Corporate Controller
Business address: 1111 S. Paca St., Baltimore, MD 21230

Godfrey A. Baker
VP of Quality
Business address: 1111 S. Paca St., Baltimore, MD 21230

Board of Directors:

BORA PHARMACEUTICALS INJECTABLES INC.

List of Board of Directors

Name:
Pao-Shi Sheng (Bobby)

Address:
6F., No. 2
Alley 36, Lane 26,
Ruiguang Road
Neihu District
Taipei City 114
Taiwan

Elected:
May 28, 2024

Attachment D

Delaware Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BORA PHARMACEUTICALS INJECTABLES INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BORA PHARMACEUTICALS INJECTABLES INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

3775199 8300

SR# 20243407545

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204155727

Date: 08-14-24

DISTRIBUTOR REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

177728 177728

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Bora Pharmaceuticals Injectables Inc.
1111 South Paca Street
Baltimore MD 21230

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Bora Pharmaceuticals Injectables Inc.
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2025)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO	EXPIRATION DATE
D07581	05/31/2025

SIGNATURE OF BEARER

177728

State of Maryland 177728

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Bora Pharmaceuticals Injectables Inc.
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2025)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D07581	05/31/2025

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Distributor Change of Information

A Distributor must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

JPMORGAN CHASE BANK, N.A.
TRADE & WORKING CAPITAL
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128
SWIFT: CHASUS33

DATE : 29 Oct 2024

IRREVOCABLE STANDBY LETTER OF CREDIT REFERENCE NO.: NUSCGS054757

TO: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

DEAR SIR/MADAM,

WE HEREBY ISSUE OUR IRREVOCABLE STANDBY LETTER OF CREDIT IN YOUR FAVOR.

BENEFICIARY	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206 RENO, NV 89521 ATTN: EXECUTIVE SECRETARY
ACCOUNT PARTY	:	BORA PHARMACEUTICALS INJECTABLES, INC. 1111 S. PACA ST. BALTIMORE, MARYLAND 21230
DATE OF EXPIRY	:	29-OCT-2025
PLACE OF EXPIRY	:	OUR COUNTER
AMOUNT	:	USD 25,000.00
APPLICABLE RULE	:	ISP LATEST VERSION

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF BORA PHARMACEUTICALS INJECTIBLES, INC., WE JPMORGAN CHASE BANK, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT NUSCGS054757 IN THE PRINCIPAL SUM OF USD 25,000.00 (TWENTY FIVE THOUSAND AND 00/100 U.S. DOLLARS) .

2. WE UNDERSTAND THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE ACCOUNT PARTY/LICENSEE.

3. WE FURTHER UNDERSTAND THAT THIS CREDIT IS INTENDED TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY ACCOUNT PARTY/ LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAWREGARDING ACCOUNT PARTY/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS BELOW.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE BY REGISTERED

MAIL, RETURN RECEIPT REQUESTED, OR COURIER.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL SEND THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFOR, AND RETURN THE DOCUMENTS TO THE BOARD.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. IT IS A CONDITION OF THIS LETTER OF CREDIT THAT IT SHALL BE AUTOMATICALLY EXTENDED WITHOUT AMENDMENT FOR ADDITIONAL ONE YEAR PERIODS FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE, UNLESS AT LEAST 60 DAYS PRIOR TO THE CURRENT EXPIRY DATE WE SEND NOTICE IN WRITING TO YOU AT THE ABOVE ADDRESS, THAT WE ELECT NOT TO AUTOMATICALLY EXTEND THIS LETTER OF CREDIT FOR ANY ADDITIONAL PERIOD. HOWEVER IN NO EVENT SHALL THIS LETTER OF CREDIT BE AUTOMATICALLY EXTENDED BEYOND THE FINAL EXPIRY DATE OF 29 OCT 2028.

12. THIS CREDIT WILL BE CANCELLED IN WHOLE OR IN PART ONLY UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD.

13. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

14. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

15. THIS CREDIT SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA AND INTERNATIONAL STANDBY PRACTICES, 1998, I.C.C. PUBLICATION NO. 590 ('ISP98'). AS TO THE MATTERS NOT COVERED BY ISP98, SHALL BE SUBJECT TO LAWS OF THE STATE OF NEVADA.

PLEASE ADDRESS ALL CORRESPONDENCE REGARDING THIS STANDBY LETTER

OF CREDIT QUOTING OUR REFERENCE NUSCGS054757 TO:
JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS 10410
HIGHLAND MANOR DRIVE, FLOOR 03,
TAMPA, FL 33610-9128.

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS054757 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,



Authorized Signature
Tahir H Rana
VP - Operations Manager

ATTACHMENT A
CERTIFICATE OF DRAWING

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: NUSCGS054757

TO: JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS
STANDBY LCS 10410 HIGHLAND MANOR DRIVE,
FLOOR 03 TAMPA, FL 33610-9128

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. PURSUANT TO NRS 639.515(4), A LAWFUL ORDER IMPOSING FINES AND/ OR COSTS AGAINST THE ACCOUNT PARTY/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. NUSCGS054757 (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF USD .....

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF DRAWING ON THIS DAY OF ...., 20...

NEVADA STATE BOARD OF PHARMACY
EXECUTIVE
BY: .....

ATTACHMENT B

CERTIFICATE FOR CANCELLATION
IRREVOCABLE STANDBY LETTER OF CREDIT NO.: NUSCGS054757

TO: JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS 10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:
1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED, OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPRIATE.
2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE# REFERENCED CREDIT.
THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF CANCELLATION ON THIS DAY OF , 20...

NEVADA STATE BOARD OF PHARMACY BY:

Attachment E

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bora Pharmaceuticals Injectables Inc.

Pharmacy/Wholesaler License # (if applicable) WH01623

Physical Address 1111 South Paca Street

City Baltimore State MD Zip 21230

Mailing Address (if different from physical address) 1111 South Paca Street, Attn: Quality Systems – Client Support

City Baltimore State MD Zip 21230

Telephone 410-843-5000 Website https://bora-corp.com

Licensing Company Email qsauditcompliance@bora-corp.com

Section 2: Personal Information

First David Middle _____ Last Fidler

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State MD Zip 21230

Telephone [redacted] Email qsauditcompliance@bora-corp.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Warwick, Warwick Business School		09/2000 - 09/2001	
Address	**City**	**State**	**Zip**
Scarman Rd, Coventry CV4 7AL, United Kingdom			
Diploma/Degree obtained, if any			
MBA			
School Name		From - To (MM/YY – MM/YY)	
University of Huddersfield		09/1985 - 06/1989	
Address	**City**	**State**	**Zip**
Queensgate, Huddersfield HD1 3DH, United Kingdom			
Diploma/Degree obtained, if any			
Btec Systems, Industrial Measurement and Control Engineering			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2015 - present	[redacted]	[redacted]	MD	21030
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Emergent BioSolutions			01/23 - Present	
Business Address		**City**	**State**	**Zip**
1111 South Paca Street		Baltimore	MD	21230
Phone	**Title**		**Number of Employed Hours**	
410-843-5000	VP/General Manager		approximately 3,250	
Description of Duties				
Site head of the Camden division business operation with responsibility for day-to-day operations.				

Business Name			From - To (MM/YY – MM/YY)	
Pii			04/22 - 01/23	
Business Address		**City**	**State**	**Zip**
10819 Gilroy Road		Hunt Valley	MD	21031
Phone	**Title**		**Number of Employed Hours**	
410-584-0001	Head of Supply Chain		approximately 750	
Description of Duties				
Responsible for supply chain consisting of GMP warehouse operations, materials management, production scheduling, technical services and procurement.				

Business Name			From - To (MM/YY – MM/YY)	
Aphena Pharma Solutions			09/19 - 02/22	
Business Address		**City**	**State**	**Zip**
7879 Industry Lane		Easton	MD	21601
Phone	**Title**		**Number of Employed Hours**	
866-465-4506	VP/General Manager		approximately 4,000	
Description of Duties				
Responsible for the liquids division business operation with full ownership of balance sheet and P&L including executing to sales budget and working with site department heads to develop CapEx planning. Recruited site leadership team to align with strategic development of GMP compliant Rx, OTC and medical device manufacturing. Responsible for tech services, manufacturing and packaging operations, engineering and maintained, supply chain and site quality functions.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

30 AUG 2024
Date

I, David Fidler, **certify that as the designated representative for**

Bora Pharmaceuticals Injectables Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DF I am at least 21 years of age;
3. DF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Fidler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30 AUG 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Fidler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30 AUG 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Baltimore City

I, David Fidler, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

30 Aug 2024

Date

Subscribed and Sworn to before me this 30 day of Aug 2024

Notary Public Signature

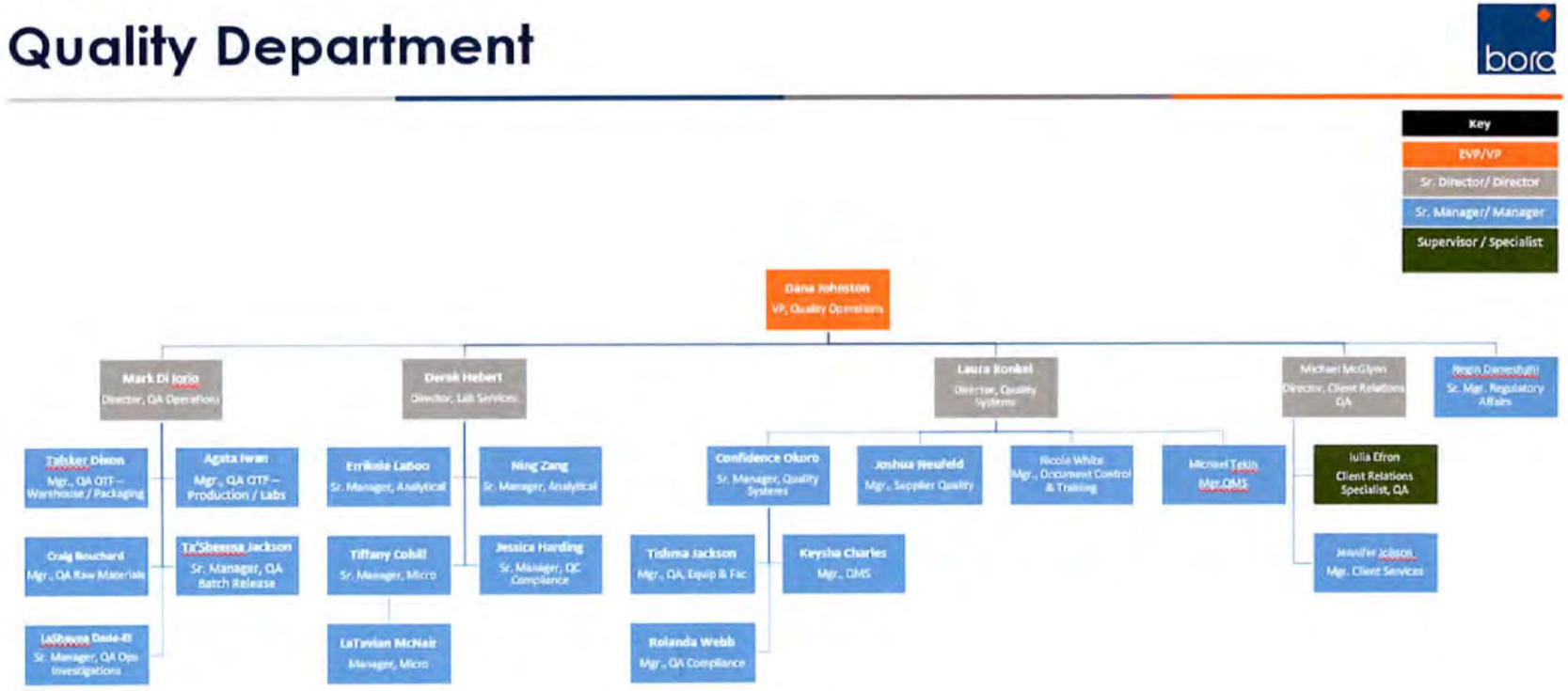
DANIELLE AUGUSTUS
Notary Public - State of Maryland
Baltimore County
My Commission Expires May 27, 2028

(Seal)

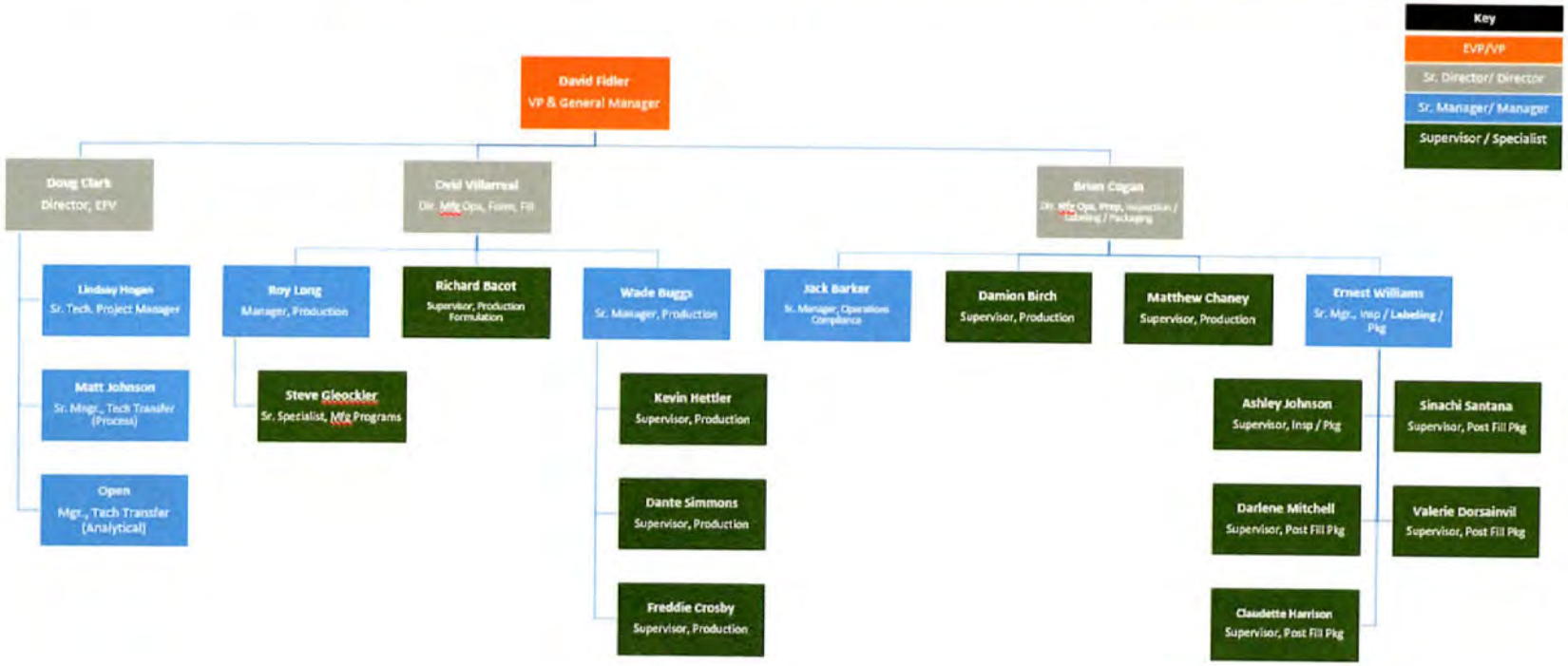
Attachment F

List of Employees

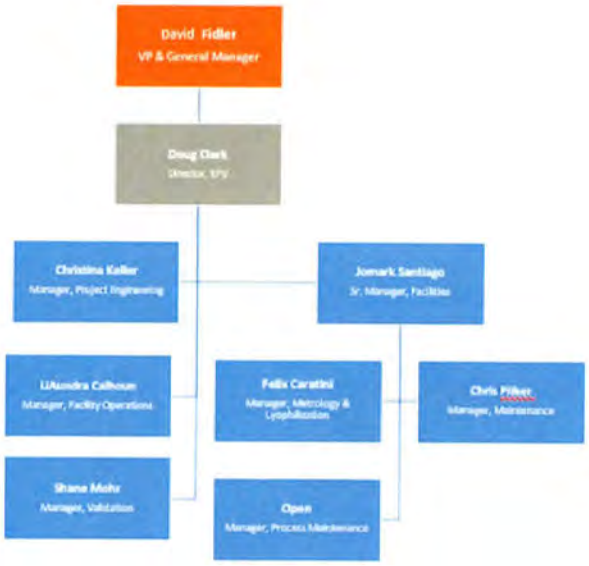
As of 29Aug2024, Bora Pharmaceuticals Injectables Inc. has 355 employees. Please see the Organizational chart below for the names of the supervisors and above.

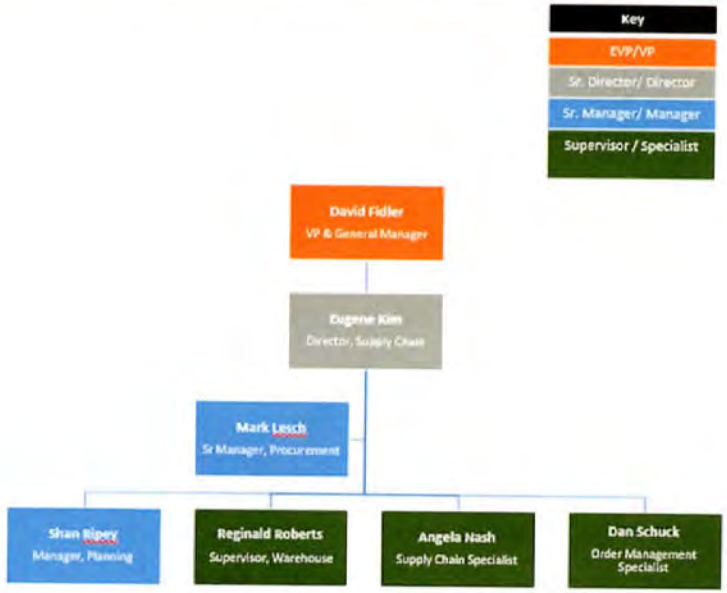


Manufacturing Operations



EFV & Supply Chain





4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: DiaSorin Inc.

Physical Address: 1951 Northwestern Avenue

City: Stillwater State: MN Zip: 55085

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 651-439-9710 Website: www.diasorin.com

Name of Designated Representative (DR): John Walter

Licensing Company Email: john.walter@diasorin.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Aug 3, 2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: ~~Minnesota~~ Delaware

Parent Company (if any): DiaSorin SpA

Corporation/Organization Name: DiaSorin Inc.

Mailing Address: 1951 Northwestern Avenue

City: Stillwater State: MN Zip: 55082

Telephone: 651-439-9710 Email: john.walter@diasorin.com

Contact Person Name: John Walter

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

DiaSorin Inc.

Facility Name

John Walter

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Aug 3, 2023

Date

Board Use Only	Date Received: ~~8/9/23~~ 1/4/24	Amount: 1000-CC

FDA

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
DIASORIN INC.
1951 Northwestern Ave
Stillwater, MN 55082
Registration Number: 2182595
FEI Number*: 2182595
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
DiaSorin Inc.[6]
1951 Northwestern Ave
Stillwater, MN US 55082
Owner/Operator Number: 9051149[7]

Official Correspondent:
Mari Meyer
1951 Northwestern Ave
Stillwater, MN 55082
Phone: 651-4399710

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Links on this page:

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2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9051149&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9051149&OwnerOperator

Page Last Updated: 09/16/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9051149&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9051149&OwnerOperator

DiaSorin The Diagnostic Specialist

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285
800-328-1482
tel 651-439-9710
fax 651-351-5669

April 2, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 106
Reno, NV 89521

Reference: Diasorin Inc. Wholesaler Application

To Whom It May Concern:

Diasorin Inc. is requesting a license to sell in vitro diagnostic devices within the state of Nevada. Please accept the enclosed applications (Wholesaler, MDEG, Designated Representative, Personal History, and supporting documentation.

If there are any questions regarding this submission, please contact Kelly Olien by email at [redacted] or by phone at 715-220-5915.

Sincerely,

Kelly Olien
Regulatory Affairs Specialist
DiaSorin Inc.

DiaSorin The Diagnostic Specialist

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285
800-328-1482
tel 651-439-9710
fax 651-351-5669

DiaSorin Inc. is 100% owned by:

DiaSorin S.p.A.
Vita Crescentino snc
13040 Saluggia (VC)
Italy

DiaSorin S.p.A. is publicly traded.

Please find the Designated Representative of DiaSorin Inc. located at 1951 Northwestern Avenue, Stillwater, MN 55082 in the table provided below.

Position	Name	Email	Phone	Work history
President	John Walter	[redacted]	651-439-9710	DiaSorin Inc. November 1992 - present

DiaSorin

The Diagnostic Specialist

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285
800-328-1482
tel 651-439-9710
fax 651-351-5669

Please find the Officers of DiaSorin Inc. located at 1951 Northwestern Avenue, Stillwater, MN 55082 in the table provided below.

Position	Name	Email	Phone
President	John Walter	[redacted]	651-439-9710
Vice President	Pedron Piergiorgio		
Secretary	Kay Williams		
Treasurer	John Hoffarth		

DiaSorin The Diagnostic Specialist

DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285
800-328-1482
tel 651-439-9710
fax 651-351-5669

DiaSorin Inc. is 100% owned by:

DiaSorin S.p.A.
Vita Crescentino snc
13040 Saluggia (VC)
Italy

DiaSorin S.p.A. is publicly traded.

Please find the Designated Representative of DiaSorin Inc. located at 1951 Northwestern Avenue, Stillwater, MN 55082 in the table provided below.

Position	Name	Email	Phone	Work history
President	John Walter	[redacted]	651-439-9710	DiaSorin Inc. November 1992 - present

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DIASORIN INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF DECEMBER, A.D. 2023.

Jeffrey W. Bullock, Secretary of State

3270133 8300

SR# 20234056244

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204709803

Date: 12-01-23

HSL Exempt

MINNESOTA
BOARD OF PHARMACY

Minnesota Board of Pharmacy
335 Randolph Ave; #230
St Paul, MN 55102
Email: pharmacy.board@state.mn.us
Protecting the Public Since 1885

7/19/2023

Regarding: DiaSorin Inc. 1951 Northwestern Ave. Stillwater, MN 55082. The entity is seeking a license in your jurisdiction

To whom it may concern:

At this time the State of Minnesota does not regulate medical device companies (manufacturers or distributors) through either the Board of Pharmacy or any other health board or division. As there is no statutory or rules reference to this, we offer the related FAQ information from our official website:

https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp

Does your Board of Pharmacy license or register medical device or medical supply manufacturers, wholesale distributors, supplies or retailers?
The Board does not license or register companies that exclusively manufacture, distribute, supply or sell medical devices or supplies. If a company that handles medical devices or supplies also manufactures or distributes drugs, it must be licensed as a drug manufacturer or drug wholesaler. Exception if the drug is coated on or embedded in the device (e.g. drug-coated stents) and the resultant product is approved by the FDA as a device, the company does not have to be licensed as a manufacturer or wholesale distributor.

DiaSorin is a medical diagnostics company which exclusively manufactures, distributes, supplies, or sells medical devices and/or supplies but not drugs. The establishment is registered as a device manufacturer with the FDA as registration number 2182595. The FDA registration site offers additional information on the items registered.

If you have any questions you may reach out to me at the MN Board of Pharmacy any time.

Thank you,

Aaron L Patterson PharmD; RPh
Pharmacy Surveyor

Minnesota Board of Pharmacy
335 Randolph Avenue
Suite 230
St. Paul, MN 55102

Direct: 651-201-2838 *Office: 651-201-2825* *Fax: 651-215-0951*

Protecting the Public Since 1885 | mn.gov/boards/pharmacy

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/02/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Services Central, Inc. Minneapolis MN Office 5600 West 83rd Street 8200 Tower, Suite 1100 Minneapolis MN 55437 USA	**CONTACT NAME:** **PHONE (A/C. No. Ext):** (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105 **E-MAIL ADDRESS:**
INSURED DiaSorin Inc. 1951 Northwestern Avenue PO Box 285 Stillwater MN 55082 USA	**INSURER(S) AFFORDING COVERAGE** / **NAIC #** **INSURER A:** Great Northern Insurance Co. 20303 **INSURER B:** Chubb National Ins Co 10052 **INSURER C:** Federal Insurance Company 20281 **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 570103441775 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			73262257	12/31/2023	12/31/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 $1,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			7356-42-25	12/31/2023	12/31/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Coll./Comp. Ded.	$1,000,000 $1,000
C	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			79880644	12/31/2023	12/31/2024	EACH OCCURRENCE AGGREGATE	$15,000,000 $15,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		2471739008	12/31/2023	12/31/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Coverage.

CERTIFICATE HOLDER

DiaSorin, Inc.
1951 Northwestern Ave.
Stillwater MN 55082 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103441775

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG DiaSorin Inc MDEG License # (if applicable) n/a

Physical Address 1951 Northwestern Avenue

City Stillwater State MN Zip 55082

Mailing Address (if different from physical address) n/a

City n/a State n/a Zip n/a

Telephone 651-439-9710 Website www.diasorin.com

Licensing Company Email n/a

Section 2: Personal Information

First John Middle C Last Walter

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1951 Northwestern Avenue

City Stillwater State MN Zip 55082

Telephone 651-439-9710 Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Mankato State University			From - To (MM/YY – MM/YY): 09/88 - 12/90
Address	City: Mankato	State: MN	Zip: 56001
Diploma/Degree obtained, if any: M.A. Biology			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any: n/a			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 12/99 - Current	Address: [redacted]	City: [redacted]	State: WI	Zip: 54017
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address: n/a	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: DiaSorin Inc.			From - To (MM/YY – MM/YY): 11/92 - Present
Business Address: 1951 Northwestern Avenue	City: Stillwater	State: MN	Zip: 55082
Phone: 651-439-9710	Title: President	Number of Employed Hours: >1500 hours	
Description of Duties: Leads the development and implementation of tactical and strategic plans. Develops and implements strategies to support business operations of the company.			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties: n/a			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone / Title		Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone / Title		Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone / Title	n a	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone / Title		Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone / Title		Number of Employed Hours
Description of Duties		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____ **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

n a

Original Signature (electronic, copies or stamps not accepted)

Jan 31, 2024
Date

I, John Walter, certify that as the MDEG Administrator for DiaSorin Inc.,

that I (initial that you have read and meet the following requirements):

1. ✓ Have a high school diploma or its equivalent;
2. ✓ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOHN WALTER
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Jan 31, 2024
Date

Board Use Only	Date Received: 2/9/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJH1011

Application/License No. _____

DIASORIN INC., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1951 Northwestern Avenue Stillwater, MN 55082, as
(Address of Applicant/Principal)
PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY, a
(Surety Company)
corporation organized under the laws of the state of CT
(State of Incorporation)
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
One Hartford Plaza Hartford, CT 06155 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 31, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of October, 2024.

APPLICANT/PRINCIPAL
DIASORIN INC.

Kay Williams
Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Richard Casas, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Carrie Peterson
Witness

SIGNED and SEALED in the presence of:

Ann Formhal
Witness Ann Formhal

Witness Bartlomiej Siepierski

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Derek J. Elston, Jennifer L. Jakaitis, Richard Casas, Rachel Fore, Aaron D. Griffin, Bartlomiej Siepierski, Christopher P. Troha, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of January 31, 2024

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DiaSorin Inc.

Pharmacy/Wholesaler License # (if applicable) n/a

Physical Address 1951 Northwestern Avenue

City Stillwater State MN Zip

Mailing Address (if different from physical address) n/a

City n/a State n/a Zip n/a

Telephone 651-439-9710 Website www.diasorin.com

Licensing Company Email n/a

Section 2: Personal Information

First John Middle C Last Walter

Alias(es, nicknames, name changes, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1951 Northwestern Avenue

City Stillwater State MN Zip 55082

Telephone 651-439-9710 Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mankato State University		9/88 – 12/90	
Address	City	State	Zip
	Mankato	MN	56001
Diploma/Degree obtained, if any			
M.A. Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
n/a			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/99 – Current	[redacted]	[redacted]	WI	54017
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
n/a				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
DiaSorin Inc.			11/92 – Present
Business Address	**City**	**State**	**Zip**
1951 Northwestern Avenue	Stillwater	MN	55082
Phone	**Title**	**Number of Employed Hours**	
651-439-9710	President	>6000 hours	
Description of Duties			
Leads the development and implementation of tactical and strategic plans. Develops and implements strategies to support business operations of the company.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			
N/A			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

h/a

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, John Walter, **certify that as the designated representative for**

DiaSorin Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JW I am at least 21 years of age;
3. JW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOHN WALTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Feb 1, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOHN WALTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Jan 31, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Anoka

I, Carrie Peterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Jan 31, 2024

Date

Subscribed and Sworn to before me this 31st day of January.

Carrie Peterson

Notary Public Signature

CARRIE A PETERSON
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site DiaSorin Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1951 Northwestern Avenue

City Stillwater State MN Zip 55082

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 651-439-9710 Website www.diasorin.com

Licensing Company Email n/a

Section 2: Personal Information

First John Middle C. Last Walter

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1951 Northwestern Avenue

City Stillwater State MN Zip 55082

Telephone 651-439-9710 Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MANKATO STATE UNIVERSITY		9/88 – 12/90	
Address	City	State	Zip
	MANKATO	MN	56001
Diploma/Degree obtained, if any			
M.A. BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
n a			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/99 - CURRENT	[redacted]	[redacted]	WI	54017
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

n a

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
DIABORDN			11/92 - PRESENT
Business Address	**City**	**State**	**Zip**
1951 NORTHLSTERN BLVD	STILLWATER	MN	55082
Phone	**Title**		
	PRESIDENT		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			
N/A			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

n a

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOHN, WALTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Aug 3, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Anoka

I, John Walter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Aug 3, 2023

Date

Subscribed and Sworn to before me this 3rd day of August 2023

Carrie A. Peterson

Notary Public Signature

CARRIE A PETERSON
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2025

(Seal)

xDate	Person ID	Employee
4/30/2024	[redacted]	Neff,T
4/30/2024		Hanson,J
4/30/2024		Hovorka,K
4/30/2024		Ducklow,B
4/30/2024		Wood,N
4/30/2024		Williams,K
4/30/2024		Hoffarth,J
4/30/2024		Olson,G
4/30/2024		Meyer,M
4/30/2024		Stewart,D
4/30/2024		Pellarin,A
4/30/2024		Walter,J
4/30/2024		Earnhardt,E
4/30/2024		Whalen,A
4/30/2024		Resech,K
4/30/2024		McConnell,J
4/30/2024		Wheeler,N
4/30/2024		Brennecke,K
4/30/2024		Sparks,B
4/30/2024		Domeyer,N
4/30/2024		Yore,S
4/30/2024		Balasubramanian,S
4/30/2024		Tounsley,R
4/30/2024		Torrey,D
4/30/2024		Hanson,K
4/30/2024		Profenno,M
4/30/2024		Cowen,J
4/30/2024		Oetter,K
4/30/2024		Rode,A
4/30/2024		Dozier,J
4/30/2024		Pieper,K
4/30/2024		Seeman,J
4/30/2024		Lee,B
4/30/2024		Cummings,S
4/30/2024		Winterfeldt,P
4/30/2024		Sandstrom,C
4/30/2024		Cicero,A
4/30/2024		Peterson,C
4/30/2024		Wassenberg,J
4/30/2024		Wendt,D
4/30/2024		Alessandria,F
4/30/2024		Breiland,T
4/30/2024		Melde,K
4/30/2024		Sobiech,R
4/30/2024		McLennan,V
4/30/2024		Cristan,N
4/30/2024		Motzko,S
4/30/2024		Nergard,J
4/30/2024		Salisbury,M
4/30/2024		Sopp,J
4/30/2024		Menssen,R
4/30/2024		Siek,K
4/30/2024		Gorsetman,J
4/30/2024		Valenty,S

4/30/2024	[redacted]	Bunnell,T
4/30/2024	[redacted]	Stewart,D
4/30/2024	[redacted]	Rivard,K
4/30/2024	[redacted]	Podgorski,A
4/30/2024	[redacted]	Belisle,K
4/30/2024	[redacted]	Granlund,J
4/30/2024	[redacted]	Hansen,M
4/30/2024	[redacted]	Bradley,W
4/30/2024	[redacted]	Guinn,C
4/30/2024	[redacted]	Mills,S
4/30/2024	[redacted]	Pfeifer,L
4/30/2024	[redacted]	Wilman,C
4/30/2024	[redacted]	Fritz,T
4/30/2024	[redacted]	Gajeski,J
4/30/2024	[redacted]	Delich,M
4/30/2024	[redacted]	Wagner,S
4/30/2024	[redacted]	Nieman,A
4/30/2024	[redacted]	Zimmerman,E
4/30/2024	[redacted]	Anderson,T
4/30/2024	[redacted]	Bowman,R
4/30/2024	[redacted]	Prendergast,J
4/30/2024	[redacted]	Lange,J
4/30/2024	[redacted]	Cheeseman,J
4/30/2024	[redacted]	Purdie,J
4/30/2024	[redacted]	Votava,V
4/30/2024	[redacted]	Underleiter,B
4/30/2024	[redacted]	Ethridge,J
4/30/2024	[redacted]	Sarggis,N
4/30/2024	[redacted]	Munn,M
4/30/2024	[redacted]	Fisher,D
4/30/2024	[redacted]	Wardach,C
4/30/2024	[redacted]	Lassere,T
4/30/2024	[redacted]	Ciancia,R
4/30/2024	[redacted]	Conchas,J
4/30/2024	[redacted]	Blomberg,D
4/30/2024	[redacted]	Sampedro,M
4/30/2024	[redacted]	Olson,J
4/30/2024	[redacted]	Holowach,D
4/30/2024	[redacted]	Cook,C
4/30/2024	[redacted]	Farago,A
4/30/2024	[redacted]	Caplan,M
4/30/2024	[redacted]	Sobotta,D
4/30/2024	[redacted]	Modahl,H
4/30/2024	[redacted]	Morris,M
4/30/2024	[redacted]	Biederman,B
4/30/2024	[redacted]	Stone,A
4/30/2024	[redacted]	Elbert,T
4/30/2024	[redacted]	Magon,A
4/30/2024	[redacted]	Prokop,J
4/30/2024	[redacted]	Woodley,J
4/30/2024	[redacted]	Kelzenberg,L
4/30/2024	[redacted]	Olien,K
4/30/2024	[redacted]	Archer,R
4/30/2024	[redacted]	Clements,A
4/30/2024	[redacted]	Chindakone,V

4/30/2024	[redacted]	Everson,J
4/30/2024		Burke,M
4/30/2024		Yang,M
4/30/2024		Gilbertson,T
4/30/2024		Wakeling,L
4/30/2024		Wenker,K
4/30/2024		Mata,D
4/30/2024		Buske,M
4/30/2024		Cwikla,K
4/30/2024		Kane,A
4/30/2024		Demko,M
4/30/2024		Timmons,C
4/30/2024		Repke,M
4/30/2024		Allen,M
4/30/2024		Nyhus,K
4/30/2024		Ralston,B
4/30/2024		Khang,C
4/30/2024		Weidner,O
4/30/2024		Bishop,Z
4/30/2024		Yang,K
4/30/2024		Richeson,E
4/30/2024		Bacon,R
4/30/2024		Howard,S
4/30/2024		Palaima,E
4/30/2024		Biebl,L
4/30/2024		Hall,L
4/30/2024		Lyons,J
4/30/2024		Kim,T
4/30/2024		Londino,J
4/30/2024		Farrell,S
4/30/2024		Green,T
4/30/2024		Maas,K
4/30/2024		Leverty,K
4/30/2024		Lins,C
4/30/2024		Johnson,A
4/30/2024		Harthorn,A
4/30/2024		Bergh,C
4/30/2024		Hilgers,K
4/30/2024		Penaloza,S
4/30/2024		Kubiszewski,M
4/30/2024		Hollister,C
4/30/2024		Vang,Y
4/30/2024		Her,L
4/30/2024		Bernardini,E
4/30/2024		Rangu,M
4/30/2024		Froehner,G
4/30/2024		Tuttle,A
4/30/2024		Dauwalter,T
4/30/2024		Poling,J
4/30/2024		Kosloski,S
4/30/2024		Sager,C
4/30/2024		Vaught,D
4/30/2024		Tigges,B
4/30/2024		Hoebbel,K
4/30/2024		Mekonnen,S

4/30/2024	[redacted]	Sawyer,W
4/30/2024	[redacted]	Tenuta,R
4/30/2024	[redacted]	Geraets,S
4/30/2024	[redacted]	Hilgers,M
4/30/2024	[redacted]	Lecander,D
4/30/2024	[redacted]	Yust,C
4/30/2024	[redacted]	Markee,L
4/30/2024	[redacted]	Shultz,C
4/30/2024	[redacted]	Bauer,L
4/30/2024	[redacted]	Quist,M
4/30/2024	[redacted]	Kaphing,J
4/30/2024	[redacted]	Shrestha,H
4/30/2024	[redacted]	Utecht,T
4/30/2024	[redacted]	Stolp,C
4/30/2024	[redacted]	Schindler,S
4/30/2024	[redacted]	Spindler,E
4/30/2024	[redacted]	Voth,P
4/30/2024	[redacted]	Brandt,D
4/30/2024	[redacted]	Cadwallader,C
4/30/2024	[redacted]	Connolly,A
4/30/2024	[redacted]	Yang,K
4/30/2024	[redacted]	Bell,A
4/30/2024	[redacted]	Ryder,L
4/30/2024	[redacted]	Passerini,J
4/30/2024	[redacted]	Nelson,T
4/30/2024	[redacted]	Hummel,R
4/30/2024	[redacted]	Menk,R
4/30/2024	[redacted]	Shapiro,R
4/30/2024	[redacted]	Sadowski,K
4/30/2024	[redacted]	Ohlin,M
4/30/2024	[redacted]	Khang,C
4/30/2024	[redacted]	Kincaid,J
4/30/2024	[redacted]	Veitch,A
4/30/2024	[redacted]	Fico,A
4/30/2024	[redacted]	Miller,J
4/30/2024	[redacted]	Morrell,R
4/30/2024	[redacted]	Nelson,C
4/30/2024	[redacted]	LeBrun,K
4/30/2024	[redacted]	Michielli,R
4/30/2024	[redacted]	Bird,N
4/30/2024	[redacted]	Shetayh,D
4/30/2024	[redacted]	Zanter,J
4/30/2024	[redacted]	Ehlenfeldt,M
4/30/2024	[redacted]	Gerber,J
4/30/2024	[redacted]	Guerra,B
4/30/2024	[redacted]	Cunningham,T
4/30/2024	[redacted]	Fox,M
4/30/2024	[redacted]	Reed,F
4/30/2024	[redacted]	Cockle,J
4/30/2024	[redacted]	Kubisiak,J
4/30/2024	[redacted]	Jenkins,K
4/30/2024	[redacted]	Damsgard,A
4/30/2024	[redacted]	Doornink,A
4/30/2024	[redacted]	Seivert,C
4/30/2024	[redacted]	Biggham,M

4/30/2024	[redacted]	Holloway,D
4/30/2024	[redacted]	McCue,W
4/30/2024	[redacted]	Blanc-Villacreses,C
4/30/2024	[redacted]	Chan,H
4/30/2024	[redacted]	Schwichtenberg,G
4/30/2024	[redacted]	Morcomb,A
4/30/2024	[redacted]	Holdstock,J
4/30/2024	[redacted]	Lachaussie,K
4/30/2024	[redacted]	Vantassel,M
4/30/2024	[redacted]	Wimmer,M
4/30/2024	[redacted]	Feneis,J
4/30/2024	[redacted]	Shukla,A
4/30/2024	[redacted]	Ciucci,M
4/30/2024	[redacted]	Kier,Z
4/30/2024	[redacted]	Imaev,T
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4/30/2024	[redacted]	Yang,M
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4/30/2024	[redacted]	Harris,D
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4/30/2024		Tanner,J
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4/30/2024		Mayek,D
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4/30/2024		Reynolds,M
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4/30/2024		Willis,D
4/30/2024		Lau,C
4/30/2024		Williams,J
4/30/2024		Keo,S
4/30/2024		Abdirahim,I
4/30/2024		Vang,K

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Exeltis USA, Inc.

Physical Address: 180 Park Ave, Suite 101

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Name of Designated Representative (DR): Vanesa Gonzalez

Licensing Company Email: regulatory.usa@exeltis.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Laboratorios Leon Farma, S.A.
Address: Calle LA Vallina, S/N City: Villaquilambre State: Spain Zip: 24193

Name: Laboratorios Liconsa, S.A.
Address: Avenida Miralcampo 7 City: Guadalajara State: Spain Zip: 19200

Name: Aspire Pharmaceuticals, Inc.
Address: 37 Veronica Avenue City: Somerset State: NJ Zip: 08873

Name: Viva Pharmaceutical, Inc.
Address: 13880 Viking Place City: Richmond, BC State: Canad Zip: V6V 1K8

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey
Parent Company (if any): EX USA Holding, Corp
Corporation/Organization Name: Exeltis USA, Inc.
Mailing Address: 180 Park Avenue, Suite 101
City: Florham Park State: NJ Zip: 07932
Telephone: 973-324-0200 Email: rsaintclair@exeltis.com
Contact Person Name: Raymond Saintclair

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Exeltis USA, Inc. is 100% owned by EX USA Holding, Corp.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** N/A	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Exeltis USA, Inc.

Facility Name

Robert Spina

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/15/2024

Date

Board Use Only	Date Received: 11/7/24	Amount: $1000 Ck. 088274

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
EXELTIS USA, INC.
Business Trade Name:
Exeltis USA Dermatology, LLC

180 PARK AVE STE 101
FLORHAM PARK, NJ 07932
Registration Number: 3008163531
FEI Number*: 3008163531
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Exeltis USA, Inc.[6]
180 Park Ave, Suite 101
Florham Park, NJ US 07932
Owner/Operator Number: 10043621[7]

Official Correspondent:
John Kim
180 Park Ave, Suite 101
Florham Park, NJ 07932
Phone: 1-973-3240200-3365

VERIFIED 11/8/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10043621&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10043621&OwnerOperatc

Page Last Updated: 11/11/2024

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U.S. Food and Drug Administration
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Silver Spring, MD 20993
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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10043621&OwnerOperatc

Exeltis USA, Inc.
180 Park Avenue, Suite 101
Florham Park, NJ 07932
Phone: 973-324-0200
Fax: 973-324-0795

27 July 2023

FDA Deregistration Notification Letter

To whom it may concern:

Exeltis USA, Inc., located at 180 Park Ave, Suite 101, Florham Park, NJ 07932, has been de-registered as a label establishment under FDA Establishment Identifier (FEI) number 0221942453. The FDA has notified Exeltis USA, Inc. that it does not need to maintain an establishment registration because no labeling operations are conducted onsite. The correct FEI # for this facility is 3008163531.

Exeltis USA, Inc. is still the NDA holder or the US affiliate of the NDA holder for the below new drug applications being marketed:

- NDA 209570 Benznidazole tablet
- NDA 205223 Nuvessa (metronidazole) vaginal gel
- NDA 211367 Slynd (drospirenone) tablet
- NDA 209405 Tyblume (levonorgestrel/ethinyl estradiol) tablets

Exeltis USA, Inc. is a corporate office only; it does not receive and store any product within the facility. These products are manufactured either at an affiliate manufacturer or a contract manufacturer and shipped to Exeltis' third-party logistics (3PL) company, Cardinal Health 105 LLC dba Specialty Pharmaceutical Services, located at 15 Ingram Blvd, La Vergne, TN 37086. All products are shipped from the 3PL to other drug wholesalers and distributors under Exeltis labeler code 0642 or 23710.

Sincerely,

Digitally signed by John C Kim
Reason: I am approving this document
Date: 2023.07.27 11:31:45 -04'00'

John C. Kim, RPh, JD
Senior Vice President, Exeltis Regulatory Affairs

Exeltis USA, Inc.
180 Park Avenue, Suite 101
Florham Park, NJ 07932
Phone: 973-324-0200
Fax: 973-324-0795

Exeltis USA, Inc.
Ownership Details

Exeltis USA, Inc. is 100% owned by EX USA Holding, Corp
Address: 180 Park Avenue, Suite 101, Florham Park, NJ 07932

List of Officers

Robert Spina, Chief Executive Officer
Address: 180 Park Avenue, Suite 101, Florham Park, NJ 07932
Phone: (862) 658-6243
E-mail: robert.spina@xiromed.com

Eduardo Fernandez, SVP – Business Development and Operations (Secretary)
Address: 180 Park Avenue, Suite 101, Florham Park, NJ 07932
Phone: (973) 324-0200 Ext. 3022
E-mail: efernandez@exeltis.com

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

EXELTIS USA, INC.
3781212000

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on December 30, 1971.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 12th day of April, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6152620135

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **EXELTIS USA, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/11/2013, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 10/07/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202410075025744
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0750321

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

180 PARK AVE STE 101 FLORHAM PARK, NJ 07932-

Reg. No.
5003682

EXELTIS USA, INC.
ATTN: BABU LAD
180 PARK AVE STE 101
FLORHAM PARK, NJ 07932-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/31/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC. 200 Public Square, Suite 3760 Cleveland, OH 44114-1824 CN105716663–GAWU-24-25	**CONTACT NAME:** **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:**
INSURED Exeltis USA, Inc. 180 Park Ave #101 Florham Park, NJ 07932	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Allianz Global Risks US Insurance Company — 35300 **INSURER B :** Atlantic Specialty Insurance Company — 27154 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CLE-006928090-22 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			USL03073624	07/01/2024	07/01/2025	EACH OCCURRENCE	$	10,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	10,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	10,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY			711017601-0003 (AOS)	08/01/2024	08/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
B	X ANY AUTO			390001609-0003 (MA)	08/01/2024	08/01/2025	BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
B	X UMBRELLA LIAB X OCCUR			711017601-0003	08/01/2024	08/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB ☐ CLAIMS-MADE			Excess over Auto Liability			AGGREGATE	$	5,000,000
	DED RETENTION $			and Employers' Liability				$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			406048013-0003	08/01/2024	08/01/2025	X PER STATUTE ☐ OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Exeltis LLC
Xiromed LLC
180 Park Avenue, Suite 101
Florham Park, NJ 07932

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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AGENCY CUSTOMER ID: CN105716663
LOC #: Cleveland

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Exeltis USA, Inc. 180 Park Ave #101 Florham Park, NJ 07932
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:

EX USA Holdings Corp
EXELTIS USA, INC.
XIROMED, LLC

ACORD 101 (2008/01)
© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 016247179

Application/License No. _____

Exeltis USA, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
180 Park Ave., Suite 101, Florham Park, NJ 07932, as
Address of Applicant/Principal
PRINCIPAL, and Liberty Mutual Insurance Company, a
Surety Company
corporation organized under the laws of the state of Massachusetts
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street, Boston, MA 02116 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 28, 2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25 day of October, 2024.

APPLICANT/PRINCIPAL

Exeltis USA, Inc.

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Rachel A. Chaveriat, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

NA

Liberty Mutual SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Rachel A. Chaveriat all of the city of Knoxville state of Tennessee each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 28th day of October 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Exeltis USA, Inc. MDEG License # (if applicable): N/A

Physical Address: 180 Park Avenue, Suite 101

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 973-324-0200 Website: www.exeltisusa.com

Licensing Company Email: regulatory.usa@exeltis.com

Section 2: Personal Information

First: Vanesa Middle: Last: Gonzalez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 180 Park Avenue, Suite 101

City: Florham Park State: NJ Zip: 07932

Telephone: [redacted] Email: vanesa.gonzalez@chemogroup.com

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Instituto de Estudios Bursátiles (IEB)		09/16 - 06/17	
Address	**City**	**State**	**Zip**
C. de Alfonso XI, 6	Retiro, Madrid	Spain	28014
Diploma/Degree obtained, if any			
Masters in Corporate Finance and Investment Banking			
School Name		From - To (MM/YY – MM/YY)	
Rey Juan Carlos University Campus of Madrid		09/12 - 06/15	
Address	City	State	Zip
P.º de los Artilleros, 38	Vicálvaro, Madrid	Spain	28032
Diploma/Degree obtained, if any			
Bachelors in Accounting and Finance			
School Name		From - To (MM/YY – MM/YY)	
IES Miguel Catalán		09/97 - 06/03	
Address	City	State	Zip
Av. de José Gárate, s/n	Coslada, Madrid	Spain	28823
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/24 - Current	[redacted]	Weehawken	NJ	07086
07/21 - 03/24		Hoboken	NJ	07030
01/14 - 07/21		Madrid	Spain	28022
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			01/23 - Present	
Business Address		**City**	**State**	**Zip**
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	**Title**		**Number of Employed Hours**	
973-324-0200	Associate Director, Supply Chain		4000	
Description of Duties				
Executed day-to-day supply chain operations, implemented and executed packaging configurations, strategized and coordinated product launches, responsible for domestic and international logistics.				

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			09/22 - 01/23	
Business Address		**City**	**State**	**Zip**
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	**Title**		**Number of Employed Hours**	
973-324-0200	Senior Manager, Supply Chain		900	
Description of Duties				
Inventory management, supply chain operations, project planning, product launch				

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			02/21 - 09/22	
Business Address		**City**	**State**	**Zip**
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	**Title**		**Number of Employed Hours**	
973-324-0200	Supply Chain Manager		3600	
Description of Duties				
Inventory management, supply chain operations, project planning, product launch				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Vanesa Gonzalez, **certify that as the MDEG Administrator for**

Exeltis USA, Inc.,

that I (initial that you have read and meet the following requirements):

1. VG Have a high school diploma or its equivalent;
2. VG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. VG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. VG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vanesa Gonzalez
Print Name (First, Last)

Vanesa Gonzalez
Original Signature (electronic, copies or stamps not accepted)

10/15/2024
Date

Board Use Only	Date Received: 11/7/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Exeltis USA, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 180 Park Avenue, Suite 101

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 973-324-0200 Website: www.exeltisusa.com

Licensing Company Email: regulatory.usa@exeltis.com

Section 2: Personal Information

First: Vanesa Middle: Last: Gonzalez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 180 Park Avenue, Suite 101

City: Florham Park State: NJ Zip: 07932

Telephone: [redacted] Email: vanesa.gonzalez@chemogroup.com

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Instituto de Estudios Bursátiles (IEB)		09/16 - 06/17	
Address	**City**	**State**	**Zip**
C. de Alfonso XI, 6	Retiro, Madrid	Spain	28014
Diploma/Degree obtained, if any			
Masters in Corporate Finance and Investment Banking			

School Name		From - To (MM/YY – MM/YY)	
Rey Juan Carlos University Campus of Madrid		09/12 - 06/15	
Address	**City**	**State**	**Zip**
P.º de los Artilleros, 38	Vicálvaro, Madrid	Spain	28032
Diploma/Degree obtained, if any			
Bachelors in Accounting and Finance			

School Name		From - To (MM/YY – MM/YY)	
IES Miguel Catalán		09/97 - 06/03	
Address	**City**	**State**	**Zip**
Av. de José Gárate, s/n	Coslada, Madrid	Spain	28823
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/24 - Current	[redacted]	Weehawken	NJ	07086
07/21 - 03/24		Hoboken	NJ	07030
01/14 - 07/21		Madrid	Spain	28022
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			01/23 - Present	
Business Address		City	State	Zip
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	Title		Number of Employed Hours	
973-324-0200	Associate Director, Supply Chain		4000	
Description of Duties				
Executed day-to-day supply chain operations, implemented and executed packaging configurations, strategized and coordinated product launches, responsible for domestic and international logistics.				

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			09/22 - 01/23	
Business Address		City	State	Zip
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	Title		Number of Employed Hours	
973-324-0200	Senior Manager, Supply Chain		900	
Description of Duties				
Inventory management, supply chain operations, project planning, product launch				

Business Name			From - To (MM/YY – MM/YY)	
Exeltis USA, Inc.			02/21 - 09/22	
Business Address		City	State	Zip
180 Park Avenue, Suite 101		Florham Park	NJ	07932
Phone	Title		Number of Employed Hours	
973-324-0200	Supply Chain Manager		3600	
Description of Duties				
Inventory management, supply chain operations, project planning, product launch				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Vanesa Gonzalez, **certify that as the designated representative for**

Exeltis USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VG I am at least 21 years of age;
3. VG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vanesa Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vanesa Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Morris

I, Vanesa Gonzalez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/21/2024

Date

Subscribed and Sworn to before me this 21 day of October.

Notary Public Signature

CAMILLE L. CRUZ
NOTARY PUBLIC OF NEW JERSEY
Commission # 50116490
My Commission Expires 11/8/2024

(Seal)

Exeltis USA, Inc. List of Employees 2024

NAME
Abdelhamid, Menna
Agrawal, Sonal
Allison, Melissa
Anthony, Stefanie
Anzer, Joan
Arelli, Grishma
Arshad, Sadia
Aslam, Syed
Au, Andy
Babani, Solomon
Baker, Leslie
Beck, James
Bennett, Joseph E
Bhaduwala, Shruti
Blake, Christopher T.
Bloemers, Christopher
Bodnar, Tiffany
Boyd, Julie
Boyer, Lisa
Bradon, Krista
Browne, Lisa
Brugger, Barbara A
Buencamino, Leilani
Butler-Hill, Carla
Buydos, Lisa
Cain, Kevin
Capawana, Catherine
Carmichael, Carolyn
Catrone, Frank
Charest, Alexandrina
Chick, Heather
Clary, David
Coole, Michelle
Cooper, Glenn
Cooper, Lorin
Couch, Sara
Cruz, Anthony
Cruz, Camille
Daiello, Lauren
Daskalov, Peter
Davis, William
Dawkins, Brandi
Dawson, Elan
DeLouise, Tiffany
Dean, Traci
Dominguez Prieto, Maria J
Durante, Christian
Eckel, Carolyn

Edwards, Elizabeth
Ellis, Karen
English, Kamila
Esparza, Priscilla
Evans, William
Fernandez, Eduardo C
Finnestead, Kim
Frederick, Robert
Fyfe, Shannon
Gallagher, Deanna
Gardiner, Victoria I
Gash, Constance
Gibson, Karen
Gilbert, Megan
Gingerelli, Alexandra
Golden, Tracee
Goldsmith, Erika
Golson, Chayla
Gonzalez, Vanesa
Gusman, Victoria
Hamilton, Sedrick
Hebert, Diane
Henderson, Darrin
Hermanson, Karen
Hicks, Kim
Hinton, Kendrick
Hoang Trien, Natalie
Holbrook, Sean
Holcomb, Emily
Hrabovsky, Michael
Iozzia, John
Jackson, Kenneth
Jahoda, Norman
Jolly, Nicoelle
Jones, Tracy
Jordan, Kirk
Kalish, Lauren
Karas, Janet
Kelly, Michael
Kilby, Camryn
Kim, John
Kleps, Kimberly
Kline, Paul Andrew
Klitzke, TallyAnn
Lambert, Kathleen
Levitz, Alexandra
Liloia, Claudia
Lowry, Gregory
Lutovsky, Laura
Mabry, Jamie

Mandacina, Larry
Manfredi, Martin
Martinez, Dilenia
Mauren, Desirea
McCluskey, Kelsey
McDermott, Abigail
McNeil, Jenny
McQueen, Lindsay
McTavish, Jessica
Merrick, Rachel
Mihal, Robert
Moore, Regan
Multerer, Traci
Munson, Daniel
Nagy, Michael
Naminski, Christina M
Niedbalski, Daniel
Oleson, Kevin R
Patel, Suchit
Patterson, Joseph
Paul, Kristin
Perez, Salustiano
Perry, Karen
Peseski, Andigone
Pineda, Kimberly
Plant, Lisa
Proctor, Maureen
Pugh, Mark
Rainer, Elizabeth
Ratliff, Eneida
Reed, Tabitha
Reis, Roberta
Rievman, Randi
Riley, Christa
Robinson, Albert
Robinson, Erin
Rodrigues, David
Rosa, Brenda L
Ruoti, Laura
Saint Clair, Raymond P
Santiago, Monica
Setliff, Caroline
Shelton, Bradford
Shrestha, Bipul
Singleton, Chinonso
Slater, Gregory
Smith, Lori
Stagliano, Daniel
Sutton, Cynthia
Swarna, Anitha

Szakacs, Robert
Thomas, Jennifer M
Tucker, Mallory
Valle, Wendy
Vaughn, Stacey
Vedral, Thomas
Ventura, Tracy
Wallace, Robert Travis
Werth, Lesley
White, Amy
Wiggins, Charles
Williams, Kendall
Wilson, Deedra
Yoder, Cathy Burke
Young, Alexandra
Young, Todd William
Zednik, Ralph
Zelonis, Jill

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Fonseca Biosciences, LLC

Physical Address: 2807 Long Beach Blvd Ste 1A

City: Long Beach Township State: NJ Zip: 08008

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 267-987-0306 Website: www.fonsecabio.com

Name of Designated Representative (DR): Michael Luby

Licensing Company Email: compliance.fonsecabiosciences DR Email: mluby@servehcp.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: HCP Concierge, LLC
Address: 310 Hansen Access Rd Ste 105 City: King of Prussia State: PA Zip: 19406
Name: Siegfried El Masnou SA
Address: Carrer Camil Fabra, 58, 08320 El Masno City: Barcelona, Spain State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): N/A
Corporation/Organization Name: Fonseca Biosciences, LLC
Mailing Address: 2807 Long Beach Blvd, Suite 1A
City: Long Beach Township State: NJ Zip: 08008
Telephone: 267-987-0306 Email: mluby@servehcp.com
Contact Person Name: Michael Luby

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓



Description of Business Operations

Fonseca Biosciences, LLC is a privately held life sciences company focusing on the acquisition and commercialization of pharmaceutical and medical products to market in the United States. Fonseca is a Virtual Manufacturer located in Long Beach Township, New Jersey. For the products the Company licenses in the US, Fonseca will outsource manufacturing and distribution operations in order to distribute products throughout the US.

Labeler - Fonseca Biosciences, LLC (118929241) NDC Labeler Code: 83709

Contact	Address	Telephone Number	Email Address
Michael Luby	Address: 2807 Long Beach Blvd Ste 1A City, State, Zip: Long Beach Township, NJ, 08008 Country: USA	+1-267-987-0306	mluby@fonsecabio.com

Labeler Detail

Name	Address	ID/FEI	Business Operations
Fonseca Biosciences, LLC	Address: 2807 Long Beach Blvd Ste 1A City, State, Zip: Long Beach Township, NJ, 08008 Country: USA	118929241	distributes drug products under own private label(Distributes human prescription drug products)

Revised 9/2023



Fonseca Labeler code: 83709

Verified
M. H 11/4/24



List of Officers

Michael Luby
CEO / Designated Representative

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "FONSECA BIOSCIENCES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "FONSECA BIOSCIENCES, LLC" WAS FORMED ON THE TWENTY-SIXTH DAY OF JUNE, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3140378 8300

SR# 20244003909

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204683096

Date: 10-21-24

Michael Watson
SECRETARY OF STATE

Office of the Secretary of State
Jackson, Mississippi

Certificate of Good Standing

I, MICHAEL WATSON, Secretary of State of the State of Mississippi, and as such, the legal custodian of the records as required by the laws of Mississippi, to be filed in my office, do hereby certify:

That on the 8th day of July, 1998, the State of Mississippi issued a Charter/ Certificate of Authority to:

PHARMACEUTICAL TRADE SERVICES INC.

That the state of incorporation is Mississippi.

That the period of duration is perpetual.

That according to the records of this office, Articles of Dissolution or a Certificate of Withdrawal have not been filed.

That according to the records of this office, a current Annual Report has been delivered to the Office of the Secretary of State.

I further certify that all fees, taxes and penalties owed to this state, as reflected in the records of the Secretary of State, have been paid and that the corporation is in existence or has authority to transact business in Mississippi.

That insofar as the records of this office are concerned, the said PHARMACEUTICAL TRADE SERVICES INC. is in good standing at this time.

Given under my hand and seal of office
the 15th day of October, 2024

Michael Watson

Certificate Number: CN24198737
Verify this certificate online at http://corp.sos.ms.gov/corpconv/verifycertificate.aspx

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0751718

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☐ wholesaler which conducts business at the following locations in this State:

2807 LONG BEACH BLVD, STE 1A LONG BEACH TWP, NJ 08008-

Reg. No.
5006465

FONSECA BIOSCIENCES LLC
2807 LONG BEACH BLVD, STE 1A
LONG BEACH TWP, NJ 08008-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 7/9/2024

Registration Number: 5006465 **Registered as:** Manufacturer

Name: FONSECA BIOSCIENCES LLC

DBA:

Address: 2807 LONG BEACH BLVD, STE 1A, LONG BEACH TWP, NJ 08008

Original Issue Date: 06/05/2024 **Expiration Date:** 01/31/2025

Current Issue Date: 06/05/2024

Disciplines: No

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. A190082884

Application/License No. _____

Fonseca Biosciences LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2807 Long Beach Blvd Suite 1A, Long Beach, NJ 08008 (Address of Applicant/Principal), as PRINCIPAL, and Capitol Indemnity Corporation (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1600 Aspen Commons, Suite 300, Middleton, WI 53562 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 03/27/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of April, 2024.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY
Capitol Indemnity Corporation

Surety Company's Representative

Timothy Steele, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Adam L. Sills CEO & President

Witness Suzanne M. Broadbent Secretary

Countersigned by:

N/A
Nevada Resident Agent

Commonwealth of Pennsylvania - Notary Seal
KRISTINA M HURLEY - Notary Public
Montgomery County
My Commission Expires February 11, 2028
Commission Number 1296043

Posted February 20, 2020

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

A190082884
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the **CAPITOL INDEMNITY CORPORATION**, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

Timothy Steele
Name of Individual

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

$25,000.00 for A190082884 on behalf of Fonseca Biosciences LLC
Bond Amount Bond Number Principal

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 15th day of May, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company, the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of September, 2022.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Todd Burrick
Chief Underwriting Officer

CAPITOL INDEMNITY CORPORATION

Adam L. Sills
Chief Executive Officer and President

STATE OF WISCONSIN }
COUNTY OF DANE } SS

On the 1st day of September, 2022 before me personally came Adam L. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York, that he is Chief Executive Officer and President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN }
COUNTY OF DANE } SS

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked, and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 1st day of April, 20 24

Suzanne M. Broadbent
Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

CIC-ePOA (Rev. 09-2022)

Organizational Chart

Michael Luby
CEO / Designated Representative

Mike serves as the CEO and Designated Representative of Fonseca Bioscience. He oversees the Virtual Manufacturing operations, including but not limited to, contract negotiations, managing outsourced manufacturing, 3PL and distribution operations.

Bio – Michael J. Luby
Founder, President & CEO, HCP Concierge
Founder, President & CEO, Fonseca Biosciences
Founder, President & CEO, BioPharma Alliance



Mike Luby is currently the founder, President & CEO of three businesses - - HCP Concierge, Fonseca Biosciences, and BioPharma Alliance. Mike brings over 30 years of pharmaceutical marketing and sales experience to these positions, including 20+ years of experience as a successful entrepreneur.

HCP Concierge is a pharmaceutical marketing logistics organization, disrupting pharmaceutical product promotion and distribution. BioPharma Alliance provides pharma and biotech companies with management consulting and syndicated data products. Fonseca Biosciences is a privately held life sciences company focusing on the acquisition and commercialization of pharmaceutical and medical products. Prior to his current endeavors, Mike co-founded and served as CEO of TargetRx, a leading pharmaceutical database and analytics company focused on helping pharmaceutical companies understand the drivers of their sales and marketing efforts. During his ten years at TargetRx, the Company succeeded in raising over $50 million in capital, securing clients in the majority of the top 30 pharmaceutical companies worldwide and delivering over $120 million in revenue on a cumulative basis. Mike is the lead author on TargetRx's patented method of analyzing the effectiveness of marketing strategies. TargetRx was acquired in late 2011. Mike has been honored with the Philadelphia Business Journal's "40 Under 40" award and selected by PharmaVOICE as one of the "100 most inspiring people in life sciences."

Prior to starting TargetRx, Mike spent 10 years at Merck & Co., Inc., where he created and executed marketing strategies for both specialty and mass-market drugs. As head of worldwide marketing for two late stage, pre-launch products at Merck (Cancidas and Invanz), Mike spearheaded global strategy and launch planning. He also served as director of new product marketing, managing the marketing strategy of early-stage drug development candidates and evaluating the potential of in-licensing opportunities from biotech companies and other external sources. His previous roles at Merck included senior marketing manager for Fosamax, marketing analyst for Vasotec and Prilosec, as well as positions focusing on marketing to managed care customers in an assignment at Merck-Medco Managed Care. Mike began his career at Merck in sales.

Mike holds a B.A. in economics from Dartmouth College and an M.B.A. from the Wharton School of the University of Pennsylvania. He serves on the advisory boards of Galileo Analytics and Medical Marketing & Media. Mike resides in Bryn Mawr, PA with his wife and four sons.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Fonseca Biosciences LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 2807 Long Beach Blvd, Suite 1A

City: Long Beach Township State: NJ Zip: 08008

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: (267) 987-0306 Website: www.fonsecabio.com

Licensing Company Email: compliance.fonsecabiosciences@gmail.com

Section 2: Personal Information

First: Michael Middle: Last: Luby

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 2807 Long Beach Blvd, Suite 1A

City: Long Beach Township State: NJ Zip: 08008

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Wharton School of Business, University of Pennsylvania		09/96 - 05/98	
Address	**City**	**State**	**Zip**
3733 Spruce Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Dartmouth College		09/86 - 06/90	
Address	**City**	**State**	**Zip**
	Hanover	NH	
Diploma/Degree obtained, if any			
Bachelors of Arts A. Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021 - Present	[redacted]	Bryn Mawr	PA	19010
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
HCP Concierge, LLC			2013 - Present
Business Address	**City**	**State**	**Zip**
310 Hansen Access Rd Ste 105	King of Prussia	PA	19406
Phone	**Title**	**Number of Employed Hours**	
(267) 987-0306	President / CEO / Founder	274,560	

Description of Duties

Oversee all aspects of the business, including pharmaceutical promotions, wholesale distribution and third-party logistics.

Business Name			From - To (MM/YY – MM/YY)
Fonseca Biosciences LLC			06/20 - Present
Business Address	**City**	**State**	**Zip**
2807 Long Beach Blvd, Suite 1A	Long Beach Township	NJ	08008
Phone	**Title**	**Number of Employed Hours**	
(267) 987-0306	President / CEO / Founder	103,080	

Description of Duties

Sole owner and operator of the business seeking promotional rights to pharmaceutical products in the US market.

Business Name			From - To (MM/YY – MM/YY)
BioPharma Alliance			2010 - Present
Business Address	**City**	**State**	**Zip**
625 Black Rock Rd	Bryn Mawr	PA	19010
Phone	**Title**	**Number of Employed Hours**	
267-987-0306	President / CEO / Founder	313,080	

Description of Duties

Sole owner and operator of business providing management consulting services to pharmaceutical and other life sciences companies.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good afternoon,

We are providing the below information requested to complete the application approval process for Fonseca Biosciences, LLC.

- We are confirming that the DR, Michael Luby, is present full time in the facility, serving in this representative capacity for only **one** wholesaler at a time and actively involved in and aware of all daily operations in one facility. According to the DR application section 7. Attached is an explanation regarding his employment and ownership with the other facilities.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Michael Luby

Original Signature (electronic, copies or stamps not accepted)

4/1/24

Date

I, Michael Luby, **certify that as the designated representative for**

Fonseca Biosciences LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Luby

Print Name (First, Last)

Michael Luby

Original Signature (electronic, copies or stamps not accepted)

4/1/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Luby

Print Name (First, Last)

Michael Luby

Original Signature (electronic, copies or stamps not accepted)

4/1/24

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Michael Luby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Michael Luby

Original Signature

4/1/24

Date

Subscribed and Sworn to before me this 1 day of April, 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
BRIAN T HURLEY - Notary Public
Montgomery County
My Commission Expires May 8, 2027
Commission Number 1289351

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Fonseca Biosciences LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2807 Long Beach Blvd Ste 1A

City: Long Beach Township State: NJ Zip: 08008

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 267-987-0306 Website: www.fonsecabio.com

Licensing Company Email: compliance.fonsecabiosciences@gmail.com

Section 2: Personal Information

First: Michael Middle: John Last: Luby

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bryn Mawr State: PA Zip: 19010

Telephone: 267-987-0306 Email: mluby@servehcp.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
The Wharton School of Business, University of Pennsylvania			09/96-05-98
Address	**City**	**State**	**Zip**
3733 Spruce Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Masters of Business Adminstration			

School Name			From - To (MM/YY – MM/YY)
Dartmouth Collage			09/86-06/90
Address	**City**	**State**	**Zip**
207 PARKHURST HALL	Hanover	NH	03755
Diploma/Degree obtained, if any			
Bachelors of Arts A, Economics			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021- Present	[redacted]	Bryan Mawr	PA	19010
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

See Designated Representative Application

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Michael Turley
Original Signature (electronic, copies or stamps not accepted)

4/1/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Luby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/1/24

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Michael Luby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/1/24

Date

Subscribed and Sworn to before me this 1 day of April, 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
BRIAN T HURLEY - Notary Public
Montgomery County
My Commission Expires May 8, 2027
Commission Number 1289352

(Seal)

Maria Herrera

From: Fonseca Biosciences <compliance.fonsecabiosciences@gmail.com>
Sent: Monday, November 4, 2024 1:06 PM
To: Maria Herrera
Subject: Re: Nevada Out-of-State Wholesaler- Fonseca Biosciences, LLC
Attachments: DE COGS FONSECA BIOSCIENCES LLC.pdf; Employment Bio 8.11.21 Mike Luby.pdf; List of Officers_FON LBT.pdf

Follow Up Flag: Follow up
Flag Status: Completed

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good afternoon,

We are providing the below information requested to complete the application approval process for Fonseca Biosciences, LLC.

- We are confirming that the DR, Michael Luby, is present full time in the facility, serving in this representative capacity for only **one** wholesaler at a time and actively involved in and aware of all daily operations in one facility. According to the DR application section 7. Attached is an explanation regarding his employment and ownership with the other facilities.
- A full employee list, all the employees in the facility pursuant to **NRS 639.500 (2)** - Michael Luby is the only employee for Fonseca Biosciences, LLC.
- Attached is the current DE Certificate of Good Standing.
- Attached is the List of all officers and directors

Please let us know if you have any further questions.

Sincerely,

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **17857**
Inspection End Date **05/20/2024**

Registration #	Category	Inspection Type	Evaluation
5006465	**Wholesale Drug/Medical Device**	**Initial**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
Fonseca Biosciences LLC		**Office Only**

Establishment Street Address	City	ZIP	County
2807 Long Beach Boulevard, Suite 1A	**Long Beach Twp**	**NJ**	**Ocean**

Establishment Mailing Address (if different)	Phone Number	Fax Number
	(267) 987-0306	

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Ryan Reighn	**B-2407**	**Operational**	**No**	

Name and Title of Designated Representative	Email
Michael Luby, President	**mluby@fonsecabio.com**

Products
☐ Prescription Drugs ☐ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices
☐ Drug-Device ☐ API ☐ Veterinary Drugs ☒ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) **TOTAL HOURS:** 05.00

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
05/20/2024	1	08:12	09:45	2	09:45	11:30	1	11:30	13:00
	3	15:00	15:30						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☐	☐	☒
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☐	☐	☒
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☐	☐	☒
(a) 4	Maintained in a clean and orderly condition	☐	☐	☒
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☐	☐	☒
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☐	☐	☒
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☐	☐	☒
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☐	☐	☒
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☐	☐	☒
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☐	☐	☒

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other drugs until they are destroyed or returned to their supplier	☐	☐	☒
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☐	☐	☒
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☒	☐	☐
(a) 2	The wholesale distributor's most recent facility inspection reports	☒	☐	☐
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☒	☐	☐

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☒	☐	☐
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☒	☐	☐
(b)	At least annually, a wholesale distributor that purchases drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☒	☐	☐
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☒	☐	☐
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☒	☐	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☒	☐	☐

		YES	NO	N/A
Note				
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				



Inspecting Official

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* See Attachment A ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02563	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: LEO Pharma Inc.

Physical Address: 7 Giralda Farms

City: Madison State: NJ Zip: 07940

Mailing Address (if different from physical address): 7 Giralda Farms

City: Madison State: NJ Zip: 07940

Telephone: (877) 494-4536 Website: www.leo-pharma.us

Name of Designated Representative (DR): Farris Edward Smith

Licensing Company Email: fasmi@leo-pharma.com DR Email: fasmi@leo-pharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☑ Others: Legend - Human Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): LEO US Holding, Inc.

Corporation/Organization Name: LEO Pharma Inc.

Mailing Address: 7 Giralda Farms

City: Madison State: NJ Zip: 07940

Telephone: (877) 494-4536 Email: fasmi@leo-pharma.com

Contact Person Name: Farris Smith

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification N/A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment C 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment D		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment E	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment F	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment G		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A. Wholly-owned by parent company.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment H	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment I	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

LEO Pharma Inc.

Facility Name

Farris Edward Smith

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

28-OCT-2024

Date

Board Use Only	Date Received: 11/6/24	Amount: $1000 CK 2058

An official website of the United States government Here's how you know

FDA

Search Result

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Current through October 17, 2024

You have searched Finished drug products

Search Results: *'leo pharma'*

Back to Search Page

RESET

Showing 1 to 16 of 16 entries

Show entries

Adbry	50222-346-02	150mg/mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	5
Adbry	50222-346-04	150mg/mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	5
Adbry	50222-346-92	150mg/mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	5
Adbry	50222-350-01	300mg/2mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	5

Adbry	50222-350-02	300mg/2mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	E
Adbry	50222-350-91	300mg/2mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA761180	LEO Pharma Inc.	E
ENSTILAR	50222-302-60	.5mg/g, 50 ug/g	AEROSOL, FOAM	TOPICAL	NDA207589	LEO Pharma Inc.	E
ENSTILAR	50222-302-66	.5mg/g, 50 ug/g	AEROSOL, FOAM	TOPICAL	NDA207589	LEO Pharma Inc.	E
ENSTILAR	50222-302-91	.5mg/g, 50 ug/g	AEROSOL, FOAM	TOPICAL	NDA207589	LEO Pharma Inc.	E
Finacea	50222-505-50	.15g/g	GEL	TOPICAL	NDA021470	LEO Pharma Inc.	E
FINACEA FOAM	50222-303-50	.15g/g	AEROSOL, FOAM	TOPICAL	NDA207071	LEO Pharma Inc.	E
FINACEA FOAM	50222-303-91	.15g/g	AEROSOL, FOAM	TOPICAL	NDA207071	LEO Pharma Inc.	E
Protopic	50222-211-30	1mg/g	OINTMENT	TOPICAL	NDA050777	LEO Pharma Inc	E
Taclonex	50222-227-04	.5mg/g, 50 ug/g	OINTMENT	TOPICAL	NDA021852	LEO Pharma Inc.	E
TACLONEX	50222-501-06	.5mg/g, 50 ug/g	SUSPENSION	TOPICAL	NDA022185	LEO Pharma Inc.	E

TACLONEX	50222-501-66	.5mg/g, 50 ug/g	SUSPENSION	TOPICAL	NDA022185	LEO Pharma Inc.	5

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

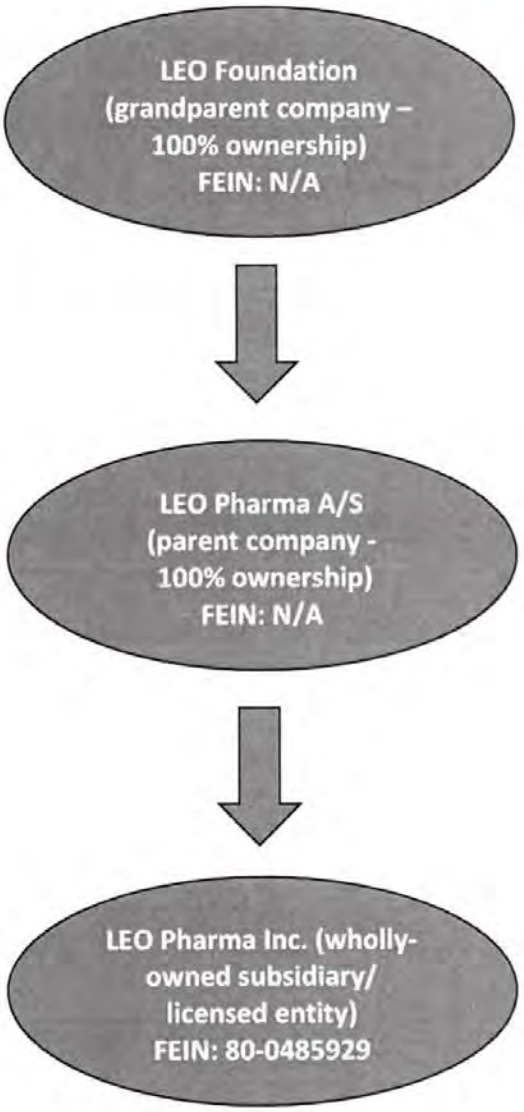
U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment A

Regarding the Ownership Restructuring

Please note that LEO Pharma Inc. has undergone an internal re-organization. The LEO family of companies created a US holding company and transferred the stock of LEO Pharma Inc. to the new holding company. **In this scenario, a holding company was created on the parent level, and the initial parent company became the grandparent company. As such, there has not been a change in ultimate control. Please also note that the FEIN # of the licensed entity has not changed.** Below please find current and previous ownership organizational charts.

Pre-Reorganization Ownership:



Post-Reorganization Ownership:



Attachment B

Nature of Business

LEO Pharma Inc. (LEO) is a virtual drug company that sells finished drug products under its labeler code and uses contract manufacturers and third-party logistics providers to manufacture and distribute its products. All products bear the LEO name and National Drug Code number (Labeler Code 50222). No pharmaceutical product is received, stored, or shipped out of its offices. Accordingly, LEO never directly handles, stores, or distributes any products.

Contact information for the manufacturing locations and third-party logistics provider are provided below.

Manufacturing sites:

LEO Laboratories Limited (t/a LEO Pharma)
285 Cashel Road, Crumlin, Dublin 12, D12E923, Ireland

LEO Pharma Manufacturing Italy SRL.
VIA Ernest Schering 21, Segrate, - 20054, Italy

ASM Aerosol-Services AG
Industriestrasse 11, 4313 Moehlin, AG, Switzerland

Catalent Indiana, LLC
1300 S Patterson Drive, Bloomington, IN 47403

Third Party Distributor:

Cardinal Health 105, LLC dba Specialty Pharmaceutical Services
15 Ingram Boulevard, LaVergne, TN 37086

Attachment E

Corporate Officer and Director Information

LEO Pharma Inc. is wholly owned by its parent company, LEO US Holdings Inc.

Officers:

Farris E. Smith
North America Vice President & CFO

Tiffany L. Christian
Secretary
NA VP Legal & Compliance

Directors:

Brian Hilberdink
Philip Eickhoff

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LEO PHARMA INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LEO PHARMA INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2009.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





4724539 8300

SR# 20243991361

Authentication: 204671243

Date: 10-18-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749660

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

7 GIRALDA FARMS MADISON, NJ 07940-

Reg. No.
5003883

LEO PHARMA INC
7 GIRALDA FARMS
MADISON, NJ 07940-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 1111602

Application/License No. _____

LEO PHARMA, INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7 Giralda Farms Madison, NJ 07940 (Address of Applicant/Principal), as PRINCIPAL, and THE HANOVER INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 440 Lincoln Street Worcester, MA 01653 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 18, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of October, 20 24.

APPLICANT/PRINCIPAL
LEO PHARMA, INC.

Authorized Representative

SURETY COMPANY
THE HANOVER INSURANCE COMPANY

Surety Company's Representative

Richard Casas, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Bartlomiej Siepiersk

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.
KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Susan A. Welsh, Christopher P. Troha, Sandra M. Winsted, Salena Wood, Christina L. Sandoval, Derek J. Elston, Judith A. Lucky-Eftimov, Aerie Walton, Bartlomiej Siepierski, Barbara Pannier, Rachel Fore, Kristin L. Hannigan, Jennifer Williams, Nicholas Kertesz, Corinne Chapman, Jean Torres, Roger Paraison, Samantha Chierici, Tara A. Maquinto, Dartonya Wright, Richard Casas, and/or Stephanie Miller

Of **AON Risk Services of Chicago, IL** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Fifty Million and No/100 ($50,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America and affirmed by each Company on March 24, 2014)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this 6th day of November, **2023**

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

Joellen M. Mendoza, Vice President

STATE OF CONNECTICUT)
COUNTY OF HARTFORD) ss

On this **6th** day of **November 2023** before me came the above named Executive Vice President and Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

Wendy Latournes
Notary Public, State of Connecticut
My Commission Expires July 31, 2025

Wendy Latournes, Notary Public
My commission expires July 31, 2025

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 18th day of October 2024

CERTIFIED COPY

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John Rowedder, Vice President

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LEO Pharma Inc.
Pharmacy/Wholesaler License # (if applicable) WH02563
Physical Address 7 Giralda Farms
City Madison State NJ Zip 07940
Mailing Address (if different from physical address) Same as physical address.
City State Zip
Telephone 877-494-4536 Website www.leo-pharma.us
Licensing Company Email fasmi@leo-pharma.com

Section 2: Personal Information

First Farris Middle Edward Last Smith
Alias(es, nicknames, name changes, etc.) N/A
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address 7 Giralda Farms
City Madison State NJ Zip 07940
Telephone 877-494-4536 Email fasmi@leo-pharma.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wake Forest High School		09/1991 - 06/1996	
Address	**City**	**State**	**Zip**
420 W Stadium Avenue	Wake Forest	NC	27587
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
University of North Carolina		09/1996 - 06/2001	
Address	**City**	**State**	**Zip**
111 Mason Farm Rd Ste 2314	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
BS ; Business Administration, BA ; Spanish			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2023-Present	[redacted]	Whippany	NJ	07981
08/2016		Toronto	~~State~~ Canada	ON M6J3B5
04/2016 - 08/2016		Toronto	~~State~~ Canada	M6K 1k1
02/2013 - 04/2016		Paris	~~State~~ France	75006
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: LEO Pharma Inc.			From - To (MM/YY – MM/YY): 08/2023 - Present
Business Address: 7 Giralda Farms	City: Madison	State: NJ	Zip: 07940
Phone: 877-494-4536	Title: North America Vice President & CFO		Number of Employed Hours: 40 hours a week
Description of Duties: Finance, Accounting, Government Pricing, Supply Chain, IT			

Business Name: Novo Nordisk			From - To (MM/YY – MM/YY): 04/2016- 08/2023
Business Address: 101 2476 Argentia Road	City: Mississauga Ontario	State: Canada	Zip: L5N 6M1
Phone: 905-629-4222	Title: CFO		Number of Employed Hours: 40 hours a week
Description of Duties: Chief Financial Officer - Finance, Supply Chain, IT, Supply Chain, Legal/Compliance			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Farris Smith, **certify that as the designated representative for**

LEO Pharma Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and/or distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Farris Smith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

28-Oct-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Farris Smith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

28-Oct-2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Farris Smith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

28-Oct-2024

Date

Subscribed and Sworn to before me this 28 day of October.

MA Del Grosso

Notary Public Signature

Marjorie A. Del Grosso
NOTARY PUBLIC
State of New Jersey
ID # 2195081
My Commission Expires 12/3/2026

(Seal)

LEO Pharma Inc. employee list

First Name	Last Name	First Name	Last Name
Lucretia	Agee	Renee	Mamouzette
Tabasum	Ahmed	Andrew	Mar
Sheetal	Alur	Leigh	Mastriani
James	Amadin	Joseph	Matson
Suzan	Aygen	James	McBride
Francis	Baez	James	Melvin
Arti	Baig	Mary Ann	Mobley
Sanjeev	Balu	Julia	Napoli
Gaurav	Bedwal	Craig	Neverosky
Greer	Below	Chinwe	Nwoye
Linda	Chiou	Maria	Ortiz-Waltner
Tiffany	Christian	Beth	Owens
Andrew	Cooper	Edna	Papasavas
Elise	Costa	Chavon	Peele
Marjorie	DelGrosso	Anabela	Pereira
Lori	DeMetro	Corinne	Pillai
Manali	Dharia	Alfred	Ponterdolph
John	Dillon	Anna	Rey
Kelsey	East	Ellen	Ribaudo
Sara	Esposito	Amanda	Ruane
Paulina	Estrada	Shannon	Schneider
Robert	Farrell	Dave	Smith
Nicole	Fontanazza	Farris	Smith
Sara	Frister	Robert	Spurr
Natalie	Gil	Evgenia	Statskaya
Ryan	Goodrich	Edgar	Suan
Elizabeth	Gory	Jessica	Swanson
Anna	Gracheva	Katherine	Swolfs
Stephanie	Halvorsen	Yolanda	Vargas
Brian	Hilberdink	Arzu	Veysel
Sadhana	Kalinani	John	Vieira
Heidi	Katz	Reena	Wade
Joseph	Levenzon	Jean	Wayman
William	Lewis	Neha	Yaduvanshi
Andrew	Lin	Thomas	Zarsky
Hannah	Lo		

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03444	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Marius Pharmaceuticals Inc

Physical Address: 2301 Sugar Bush Road, Suite 510

City: Raleigh State: NC Zip: 27612

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 919-374-1913 Website: https://mariuspharma.com/

Name of Designated Representative (DR): Nita Nimmons

Licensing Company Email: compliance.mariuspharma@gmail.com DR Email: nita@mariuspharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☒ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Nita Nimmons — 10/08/2024

Original Signature (electronic, copies or stamps not accepted) — Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: J. Knipper & Company

Address: 1250 Patrol Road City: Charlestown State: IN Zip: 47111

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): see attached list of owners

Corporation/Organization Name: Marius Pharmaceuticals Inc

Mailing Address: 2301 Sugar Bush Road, Suite 510

City: Raleigh State: NC Zip: 27612

Telephone: 919-374-1913 Email: compliance.mariuspharma@gmail.com

Contact Person Name: Nita Nimmons

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

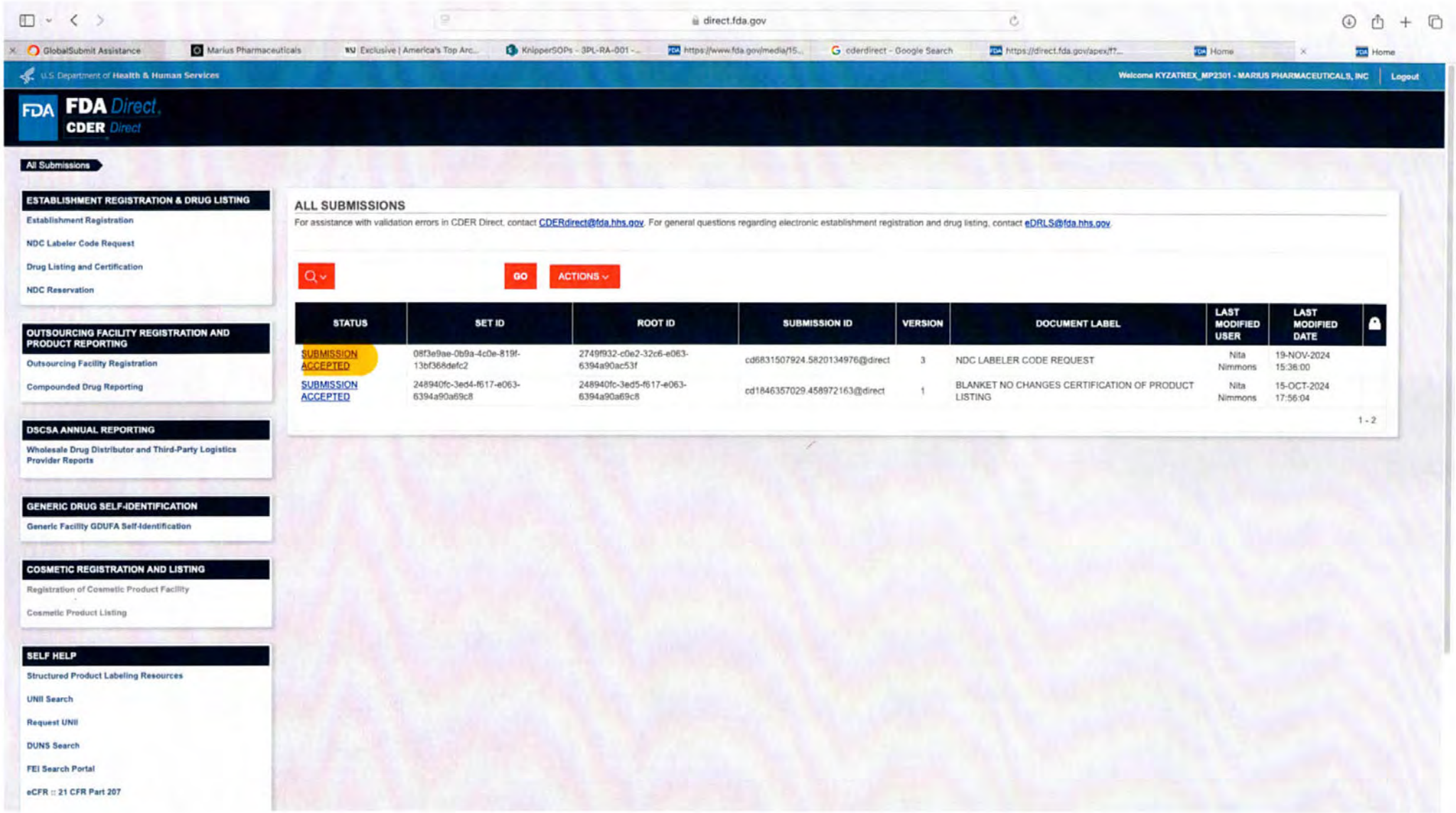
Marius Pharmaceuticals Inc
Facility Name

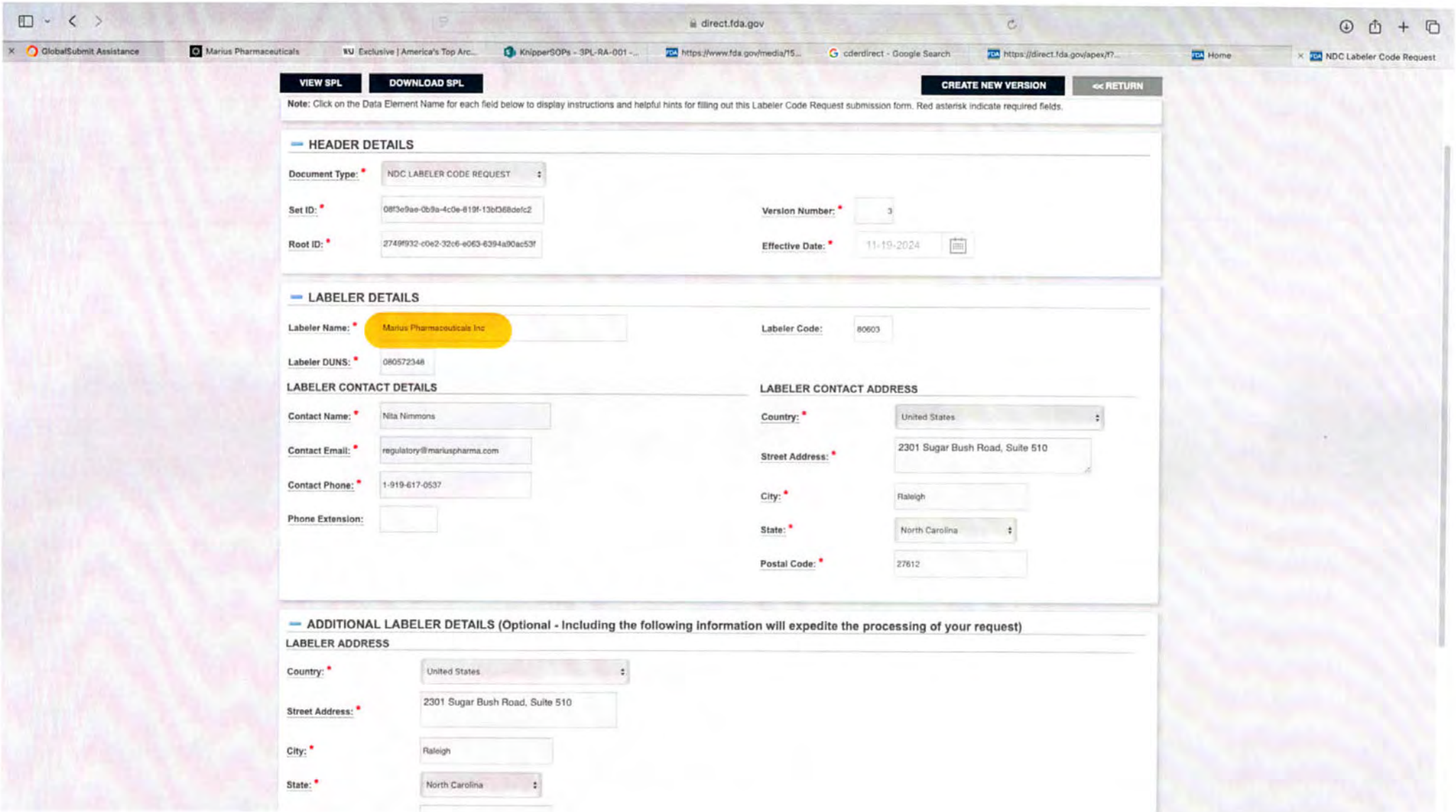
Nita Nimmons
Print Name of Authorized Person Submitting Application

Nita Nimmons
Original signature of Authorized Person (copies or stamps not accepted)

10/08/2024
Date

Board Use Only	Date Received: 10/24/24	Amount: $1000-CK#13252


direct.fda.gov
GlobalSubmit Assistance
Marius Pharmaceuticals
Exclusive | America's Top Arc...
KnipperSOPs - 3PL-RA-001 -...
https://www.fda.gov/media/15...
cderdirect - Google Search
https://direct.fda.gov/apex/f?...
Home
Home
U.S. Department of Health & Human Services
Welcome KYZATREX_MP2301 - MARIUS PHARMACEUTICALS, INC
Logout
FDA Direct
CDER Direct
All Submissions
ESTABLISHMENT REGISTRATION & DRUG LISTING
Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation
OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
Outsourcing Facility Registration
Compounded Drug Reporting
DSCSA ANNUAL REPORTING
Wholesale Drug Distributor and Third-Party Logistics Provider Reports
GENERIC DRUG SELF-IDENTIFICATION
Generic Facility GDUFA Self-Identification
COSMETIC REGISTRATION AND LISTING
Registration of Cosmetic Product Facility
Cosmetic Product Listing
SELF HELP
Structured Product Labeling Resources
UNII Search
Request UNII
DUNS Search
FEI Search Portal
eCFR :: 21 CFR Part 207
ALL SUBMISSIONS
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov.
GO
ACTIONS
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
DOCUMENT LABEL
LAST MODIFIED USER
LAST MODIFIED DATE
SUBMISSION ACCEPTED
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3
NDC LABELER CODE REQUEST
Nita Nimmons
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SUBMISSION ACCEPTED
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1
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
Nita Nimmons
15-OCT-2024 17:56:04
1 - 2


direct.fda.gov
GlobalSubmit Assistance
Marius Pharmaceuticals
Exclusive | America's Top Arc...
KnipperSOPs - SPL-RA-001 -...
https://www.fda.gov/media/15...
cderdirect - Google Search
https://direct.fda.gov/apex/f?...
Home
NDC Labeler Code Request
VIEW SPL
DOWNLOAD SPL
CREATE NEW VERSION
<< RETURN
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.
HEADER DETAILS
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Set ID: * 08f3e9ae-0b9a-4c0e-819f-13bf368defc2
Version Number: * 3
Root ID: * 2749f932-c0e2-32c6-e063-6394a90ac53f
Effective Date: * 11-19-2024
LABELER DETAILS
Labeler Name: * Marius Pharmaceuticals Inc
Labeler Code: 80603
Labeler DUNS: * 080572348
LABELER CONTACT DETAILS
Contact Name: * Nita Nimmons
Contact Email: * regulatory@mariuspharma.com
Contact Phone: * 1-919-617-0537
Phone Extension:
LABELER CONTACT ADDRESS
Country: * United States
Street Address: * 2301 Sugar Bush Road, Suite 510
City: * Raleigh
State: * North Carolina
Postal Code: * 27612
ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)
LABELER ADDRESS
Country: * United States
Street Address: * 2301 Sugar Bush Road, Suite 510
City: * Raleigh
State: * North Carolina

Marius Pharmaceuticals Inc

Facility Information: Domestic & Foreign Facility Affiliates

Name	CMO/3PL	Address	Phone Number	Email Address
Procaps SA US Generics Program	CMO	Calle 80 Barranquilla Columbia ATL 080001	+57 + 5 + 3719 456	monterroza@procaps.com
J. Knipper & Company	3PL	1250 Patrol Rd Charlestown, IN 47111	1-812-406-2321	

Marius Pharmaceuticals Inc

List of Owners/Officers:

Name	Title	Address	DOB	SSN/FEIN	Ownership %	Email ID	Phone No
Himanshu Shah	Co-CEO/ Chairman	[redacted]			28%	himanshu@mariuspharma.com	919-719-6363
Shalin Shah	Co-CEO/ CFO				13%	shalin@mariuspharma.com	919-719-6373
SOV Therapeutics Inc	-	101 Guymon Ct Raleigh, NC 27560	-	27-0595893	31%		919-678-9056
Shah Capital Opportunity Fund LP	-	8601 Six Forks Rd Raleigh, NC 27615	-	51-0570114	18%	info@shahcapital.com	919.719.6360
LOWT LLC	-	137 N Croskey St Philadelphia PA 19103		81-4729402	10%		973-223-7163

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EXHIBIT A

The names and address of the initial members of the Board of Directors are as follows:

Chairman – Himanshu H Shah

2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

Amit Shah

2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

Om Dhingra

2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

Ramesh Mahalingham

2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

Shalin Shah

2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MARIUS PHARMACEUTICALS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MARIUS PHARMACEUTICALS LLC" WAS FORMED ON THE TENTH DAY OF NOVEMBER, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6212074 8300

SR# 20240084279

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202564497

Date: 01-10-24

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State of Delaware
Secretary of State
Division of Corporations
Delivered 12:06 PM 10/01/2024
FILED 12:06 PM 10/01/2024
SR 20243832050 - File Number 6212074

CERTIFICATE OF CONVERSION FROM A LIMITED LIABILITY COMPANY TO A CORPORATION PURSUANT TO SECTION 265 OF THE DELAWARE GENERAL CORPORATION LAW

1. The jurisdiction where the Limited Liability Company was first formed is Delaware.
2. The jurisdiction immediately prior to filing this Certificate is Delaware.
3. The date the Limited Liability Company first formed is November 10, 2016.
4. The name of the Limited Liability Company immediately prior to filing this Certificate is Marius Pharmaceuticals LLC.
5. The name of the Corporation as set forth in the Certificate of Incorporation is Marius Pharmaceuticals, Inc.

IN WITNESS WHEREOF, the undersigned, being duly authorized to sign on behalf of the converting Limited Liability Company have executed this Certificate on the 1st day of October, A.D. 2024.

Marius Pharmaceuticals, LLC

DocuSigned by:
By: _____
Name: Shalin Shah
Title: CEO

[INSERT COPY OF CERTIFICATE OF INCORPORATION]

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CERTIFICATE OF INCORPORATION OF MARIUS PHARMACEUTICALS, INC.

I, the undersigned, for the purpose of creating and organizing a corporation under the provisions of and subject to the requirements of the General Corporation Law of the State of Delaware (the "**DGCL**"), certify as follows:

1. The name of the corporation is Marius Pharmaceuticals, Inc. (the "**Corporation**").

2. The address of the registered office of the Corporation in the State of Delaware is 838 Walker Road, Suite 21-2, Dover, Delaware 19904. The name of the registered agent of the Corporation at such address is Registered Agent Solutions, Inc.

3. The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

4. (a) The total number of shares of stock which the Corporation is authorized to issue is Eighty Million (80,000,000) of which Seventy-Five Million (75,000,000) shares are classified as common stock, par value 0.01 per share ("**Common Stock**"), and Five Million (5,000,000) shares are classified as preferred stock, par value 0.01 per share ("**Preferred Stock**").

(b) The Board of Directors is hereby expressly authorized to provide, out of the unissued shares of preferred stock, for one or more series of preferred stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional, or other special rights, if any, and any qualifications, limitations, or restrictions thereof, of the shares of such series. The powers, preferences, and relative, participating, optional, and other special rights of each series of preferred stock, and the qualifications, limitations, or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding.

5. The name and mailing address of the incorporator of the Corporation (the "**Incorporator**") is:

Name	Mailing Address
Shalin Shah	2301 Sugar Bush Rd., Ste 510, Raleigh, NC 27612

6. (a) The powers of the Incorporator shall terminate upon the filing of this Certificate of Incorporation.

(b) The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors.

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:06 PM 10/01/2024
FILED 12:06 PM 10/01/2024
SR 20243832050 - File Number 6212074

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(c) The names and addresses of the intial board of directors (the "**Board of Directors**") are attached in **Exhibit A**.

(d) Hereafter, any change to the number of directors which shall constitute the Board of Directors shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board of Directors.

(e) Subject to the rights of the holders of any series of Preferred Stock to elect directors under specified circumstances, directors shall be elected at each annual meeting of stockholders. Each director shall hold office until the next annual meeting of stockholders and thereafter until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

(f) Subject to any limitations imposed by applicable law and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by applicable law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

7. Unless and except to the extent that the by-laws of the Corporation (the "**By-Laws**") shall so require, the election of directors of the Corporation need not be by written ballot.

8. To the fullest extent permitted by law, a director or officer of the Corporation shall not be personally liable to the Corporation or to its stockholders for monetary damages for any breach of fiduciary duty as a director or officer. No amendment to, modification of, or repeal of this Paragraph 8 shall apply to or have any effect on the liability or alleged liability of any director or officer of the Corporation for or with respect to any acts or omissions of such director or officer occurring prior to such amendment.

9. The Corporation shall indemnify, advance expenses, and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "**Covered Person**") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "**Proceeding**"), by reason of the fact that the Covered Person, or a person for whom the Covered Person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee, or agent of another corporation or of a partnership, joint venture, trust, enterprise, or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence,

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except for claims for indemnification (following the final disposition of such Proceeding) or advancement of expenses not paid in full, the Corporation shall be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person only if the commencement of such Proceeding (or part thereof) by the Covered Person was authorized in the specific case by the board of directors of the Corporation. Provided further, that prepaymnent of exepsense shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Paragraph 9 or otherwise. Despite the foregoing, the Corporation shall not be reqired to pay any expenses in connection with any Proceeding (or part thereof) commenced by the Corporation against such Covered Person. Any amendment, repeal, or modification of this Paragraph 9 shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification.

10. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, amend, or repeal the By-Laws or adopt new by-laws without any action on the part of the stockholders; provided that any by-law adopted or amended by the board of directors, and any powers thereby conferred, may be amended, altered, or repealed by the stockholders.

11. The Corporation shall have the right, subject to any express provisions or restrictions contained in this Certificate of Incorporation of the Corporation (the "**Certificate of Incorporation**") or the By-Laws, from time to time, to amend, alter, or repeal any provision of the Certificate of Incorporation in any manner now or hereafter provided by law, and all rights and powers of any kind conferred upon a director or stockholder of the Corporation by the Certificate of Incorporation or any amendment thereof are conferred subject to such right.

12. Unless prohibited by the DGCL or this Certificate of Incorporation, the Corporation shall have the authority to enter into shareholder rights agreements with some or all current or future shareholders setting forth specific rights conferred to such shareholders.

13. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have subject matter jurisdiction, the federal district court for the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee, or stockholder of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the Certificate of Incorporation, or the By-Laws (as either may be amended or restated) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Paragraph 13.

14. Notwithstanding any other provisions of this Certificate of Incorporation or any provision of applicable law which might otherwise permit a lesser vote or no vote, but in

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addition to any affirmative vote of the holders of any particular class or series of the capital stock of the Corporation required by law or by this Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Paragraphs 7 ,8 or 9.

[SIGNATURE PAGE FOLLOWS]

Docusign Envelope ID: A5BB7AB1-7633-4DCF-97F9-C3E209B55330

I, THE UNDERSIGNED, being the incorporator, for the purpose of forming a corporation pursuant to the DGCL, do make this Certificate of Incorporation, hereby acknowledging, declaring, and certifying that the foregoing Certificate of Incorporation is my act and deed and that the facts herein stated are true, and have accordingly hereunto set my hand this 1st day of October, 2024.

Incorporator

DocuSigned by:

By _____

Name: Shalin Shah

2024

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1713

NOT TRANSFERABLE
STATUTE GS 81.106.119

LICENSE/CERTIFICATE: Virtual Manufacturer
TYPE

Expiration Date 12/31/2024

ENSEE MARIUS PHARMACEUTICALS LLC
RTIFICATOR 2301 SUGAR BUSH ROAD STE 510
RALEIGH NC 27612

LICENSED
2024
NORTH CAROLINA

IS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

3PL

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-21-2023

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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Form DEA-223 (9/2016)

Liberty Mutual SURETY

BOND RIDER

To be attached to and form a part of :

Bond No.: **268017192**

Cross Ref Bond No.: _____

Type of Bond: Pharmaceutical Wholesaler Surety Bond

Dated effective: December 19, 2022

Executed by: Marius Pharmaceuticals LLC

_____, as Principal,

And by: The Ohio Casualty Insurance Company, as Surety,

In favor of: Nevada State Board of Pharmacy

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to:

Changing: Principal Name and/or Address

From: Marius Pharmaceuticals LLC
2301 Sugar Bush Rd, Ste # 510, Raleigh, NC 27612

To: Marius Pharmaceuticals, Inc.
2301 Sugar Bush Rd, Ste # 510, Raleigh, NC 27612

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

The Principal as changed by this Rider is the Principal as if it had been initially named the Principal when the bond was issued. The former Principal is hereby released and has no obligations with respect to the bond.

This rider is effective: November 19, 2024

Signed and Sealed on: November 19, 2024

Principal Name: Marius Pharmaceuticals, Inc.

By: _____

Surety Name: The Ohio Casualty Insurance Company

By: Timothy A. Mikolajewski
Timothy A. Mikolajewski

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

Agency Name: Marsh & McLennan Agency Agency LLC

Agency Address: 20 N Martingale Rd Ste 100, Schaumburg, IL 60173-2423

Liberty Mutual SURETY

POWER OF ATTORNEY

The Ohio Casualty Insurance Company

Principal: Marius Pharmaceuticals, Inc
Agency Name: Marsh & McLennan Agency Agency LLC Bond Number: 268017192
Obligee: Nevada State Board of Pharmacy
Bond Amount: ($25,000.00) Twenty-five Thousand Dollars And Zero Cents

KNOW ALL PERSONS BY THESE PRESENTS: that The Ohio Casualty Insurance Company, a corporation duly organized under the laws of the State of New Hampshire (herein collectively called the "Company"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint **Timothy A. Mikolajewski** in the city and state of **Seattle, WA**, each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Company in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Company and the corporate seal of the Company has been affixed thereto this 1st day of August, 2024.

The Ohio Casualty Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA
COUNTY OF MONTGOMERY ss

On this 1st day of August, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of The Ohio Casualty Insurance Company and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-law and Authorizations of The Ohio Casualty Insurance Company, which is now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature or electronic signatures of any assistant secretary of the Company or facsimile or mechanically reproduced or electronic seal of the Company, wherever appearing upon a certified copy of any power of attorney or bond issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of The Ohio Casualty Insurance Company do hereby certify that this power of attorney executed by said Company is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Company this 19th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Marius Pharmaceuticals Inc
Pharmacy/Wholesaler License # (if applicable) WH03444
Physical Address 2301 Sugar Bush Road, Suite 510
City Raleigh State NC Zip 27612
Mailing Address (if different from physical address) same as above
City State Zip
Telephone 919-374-1913 Website https://mariuspharma.com/
Licensing Company Email compliance.mariuspharma@gmail.com

Section 2: Personal Information

First Nita Middle Nicole Last Nimmons
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address 2301 Sugar Bush Road, Suite 510
City Raleigh State NC Zip 27612
Telephone [redacted] Email compliance.mariuspharma@gmail.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: John Hopkins University			From - To (MM/YY – MM/YY): 01/20 - 05/22
Address: 3400 N. Charles Street	City: Baltimore	State: MD	Zip: 21218
Diploma/Degree obtained, if any: Master of Science in Regulatory Science			
School Name: East Carolina University			From - To (MM/YY – MM/YY): 08/96 - 12/00
Address: East 5th Street	City: Greenville	State: NC	Zip: 27858
Diploma/Degree obtained, if any: B.S. in Biology			
School Name: Rockingham County Sr High School			From - To (MM/YY – MM/YY): 08/92 - 06/96
Address: 180 High School Road	City: Reidsville	State: NC	Zip: 27320
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 - Current	[redacted]	Raleigh	NC	27615
08/08 - 07/19		Greenville	NC	27834

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Marius Pharmaceuticals Inc				From - To (MM/YY – MM/YY): 09/22 - Current
Business Address: 2301 Sugar Bush Road, Suite 510		City: Raleigh	State: NC	Zip: 27612
Phone: 919-374-1913	Title: Director, Quality and Regulatory			Number of Employed Hours: 400
Description of Duties: please see the attached resume				

Business Name: Amris Consulting				From - To (MM/YY – MM/YY): 09/21 - 09/22
Business Address: PO Box 173		City: Pinelevel	State: NC	Zip: 27568
Phone: 919-422-8698	Title: Quality Consultant			Number of Employed Hours: 2,000
Description of Duties: Quality Document Creation				

Business Name: Alcamil Corporation Inc				From - To (MM/YY – MM/YY): 02/19 - 09/21
Business Address: 4620 Creekston Drive		City: Durham	State: NC	Zip: 27703
Phone: 919-957-5500	Title: Quality Manager			Number of Employed Hours: 5,120
Description of Duties: see attached resume				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Nita Nimmons
Raleigh, NC 27615
[redacted]

SUMMARY

Quality and Regulatory Affairs Director, with 19 years' experience in operating and managing in a cGMP pharmaceutical and environmental environment. A result-oriented individual, with experience across many disciplines and industries. Excellent skills in communication, collaboration, and organization while demonstrating managerial skills in a highly productive workforce.

TECHNICAL COMPETENCIES

Microsoft Office • Excel • SAP • Trackwise • MasterControl • Procal • Empower 3 • LIMS • ELN • Technical Writing • Manuscript Preparation • Physical Chemical & Analytical Methods of Analysis • Minitab • FTIR Spectroscopy • HPLC • GC • UV-Vis Spectrometry • Dissolution • Moisture Titration • TLC • Microsoft D365

PROFESSIONAL EXPERIENCE

Marius Pharmaceuticals, LLC — September, 2022 to Current
Raleigh, North Carolina

Director, Quality and Regulatory

- Oversee and manage all Quality and Regulatory activities.
- Review and approve all internal and external Quality documents.
- Lead Quality Review Board meetings.
- Perform batch release.
- Perform internal and external audit.
- Oversee and perform quarterly and annual regulatory submissions.
- Host regulatory audits.
- Oversees site training and training program.
- Manage company Quality Agreements.
- Oversee management of product quality complaints and adverse event reporting.

AMRIS Consulting, LLC — 2021 to September, 2022

Quality Documents Consultant at Medicago for the Supply Chain Department
Durham, North Carolina

- Manage all Quality related documents (SOPs, Deviations, CAPAs and Change Controls).
- Assist in compiling and reporting monthly KPIs.
- Ensure timely closure of all Quality documents.

Nita Nimmons
Raleigh, NC 27615
[redacted]

Alcami Corporation, Inc.
Durham, North Carolina

2019 to September, 2021

Manager, Quality

- Oversees Laboratory Quality Operations for two Alcami sites.
- Manages a team of 11 individuals responsible for GMP Data Review and Quality document approvals (Laboratory Investigations/Deviations/SOP/Equipment Qualification, etc.).
- Works within 21 CFR Part 11, 210, 211 and 820 regulations, and ICH requirements.
- Hosts Regulatory Inspections and finalize response letter.
- Hosts ~20 internal client audits yearly.
- Assists with regulatory inspections for sister sites.
- Perform Quality review and approval of Lab Investigations, Deviations, SOPs, CAPAs, Effectiveness Checks, Extension requests, Equipment Qualifications, Computer Systems Validations, and Compliance Reports
- Ensures timely completion and compliance with cGMP and all company training requirements.
- Generate metrics and participates in monthly and quarterly quality council meetings.
- Oversees and performs internal audits of Laboratory Operations.
- Provides Quality communication for site Town Halls.
- Communicates with operations management and client Quality departments on priority needs.

Novartis Pharmaceuticals (Formerly Sandoz, Inc.)
Wilson, North Carolina

2003 to 2019

Quality Control, Manager (Finished Product and Stability)

2018 to 2019

- Managed 35 direct reports.
- Reviewed and approved departmental deviations and investigations.
- Attend Business Unit weekly meetings to align and communicate site priorities.
- Performed SOP review and approval.
- Performed FDA readiness activities.
- Performed department review and approval of validation protocols and reports.
- Led laboratory tours for FDA and internal audits as subject matter expert for the stability department and Quality Control laboratory.
- Participated in Field Alert activities for Quality Control events.
- Assisted in the implementation of Lean Lab and self-directed teams.
- Lean Six Sigma/Green Belt certification – project to enhance Lean Lab Excellence.

Quality Control Stability Manager (Stability Lead)

2013 to 2018

- Certified deviation investigation writer.
- Responsible for assessment stability chamber excursions and impact assessment.
- Responsible for stability chamber maintenance and timely calibrations.
- Review for stability data to ensure compliance with site Standard Operating Procedures.

Nita Nimmons
Raleigh, NC 27615
(252) 341-3018 (mobile)
nitanimmons@yahoo.com

- Write and update Quality Control SOPs, methods, specification forms, stability protocols, and post approval commitments to comply with all in-house procedures and/or ICH Guidelines.
- Write and execute Change Controls through change management system.
- Create, review and approve LIMS builds for stability placement.
- Maintain and manage the FUST (Follow-Up Stability) Program.
- Provide stability reports to requesting departments.
- Mitigate communication between stability department and third-party contract laboratories.
- Develop stability protocols, manage stability studies and data reporting to external clients.
- Generate stability reports for completed studies, compiling analytical data, associated temperature/humidity excursions, and associated deviations and/or laboratory investigations.

Quality Control Supervisor, QC Finished Products 2008 to 2013

- Certified laboratory investigation writer, responsible for assessing potential assignable causes and determining root cause for effective corrective and preventive actions.
- Responsible for assessing laboratory data prior to release against release and stability specification and internal release action limits.
- Participated in FDA audits as a scribe and subject matter expert for the Quality Control Laboratory and FDA remediation projects within the laboratory.
- Write and update Quality Control Standard Operating Procedures, internal monographs, and Method Validation Protocols and Reports.
- Perform Internal Laboratory Audits to ensure continued compliance.
- Executed an FMEA (Failure Mode and Effect Analysis) for QC Laboratory to eliminate sources of contamination
- Participated in the restructuring of the laboratory work flow and the addition of a sample control center

Group Lead, QC Finished Products 2003 to 2008

- Led and developed a group of 11 QC chemists.
- Promoted from Chemist I up to Chemist III/Lead within 4 years.
- Performed and led analysts in testing proprietary pharmaceuticals according to cGMP guidelines and regulations.

Environment 1, Inc. 2001 to 2003
Greenville, North Carolina

Environmental Chemist

- Performed analyses on wastewater and drinking water, to include testing for Nitrogen, Nitrates. Phosphate, conductivity, biological oxygen dissolved, oil and grease, focal coli form, and ammonia.

Nita Nimmons
Raleigh, NC 27615
[redacted]

EDUCATION

Master of Science in Regulatory Science, 2022
Johns Hopkins University, Baltimore Maryland

Bachelor's Degree in Biology, 2000
East Carolina University, Greenville North Carolina

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Nita Nimmons — Nita Nimmons

Original Signature (electronic, copies or stamps not accepted)

10/08/2024

Date

I, Nita Nimmons, **certify that as the designated representative for**

Marius Pharmaceuticals Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NN I am at least 21 years of age;
3. NN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nita Nimmons
Print Name (First, Last)

Nita Nimmons
Original Signature (electronic, copies or stamps not accepted)

10/08/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nita Nimmons
Print Name (First, Last)

Nita Nimmons
Original Signature (electronic, copies or stamps not accepted)

10/08/2024
Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake County

I, Nita Nimmons, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nita Nimmons Nita Nimmons
Original Signature

10/08/2024
Date

Subscribed and Sworn to before me this 8 day of Oct., 2024

Paula J. Andrews
Notary Public Signature

Paula J. Andrews NOTARY PUBLIC Wake County, N.C.
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Marius Pharmaceuticals Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03444

Physical Address: 2301 Sugar Bush Road, Suite 510

City: Raleigh State: NC Zip: 27612

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 919-374-1913 Website: https://mariuspharma.com/

Licensing Company Email: compliance.mariuspharma@gmail.com

Section 2: Personal Information

First: Shalin Middle: Yogesh Last: Shah

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 2301 Sugar Bush Road, Suite 510

City: Raleigh State: NC Zip: 27612

Telephone: [redacted] Email: compliance.mariuspharma@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		2004 - 2008	
Address	**City**	**State**	**Zip**
New Brunswick, NJ	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
BS Finance			

School Name		From - To (MM/YY – MM/YY)	
JP Stevens High School		2000 - 2004	
Address	**City**	**State**	**Zip**
New Dover Road	Edison	NJ	08870
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - Current	[redacted]	Raleigh	NC	27607
05/14 - 07/20	[redacted]	Raleigh	NC	27609
08/12 - 04/14	[redacted]	Raleigh	NC	27609
1993 - 07/12	[redacted]	Edison	NC	08870
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Marius Pharmaceuticals Inc			From - To (MM/YY – MM/YY): 1/1/17 - Current
Business Address: 2301 Sugar Bush Road, Suite 510	City: Raleigh	State: NC	Zip: 27612
Phone: 919-374-1913	Title: CEO		
Description of Duties: see attached resume			

Business Name: Shah Capital			From - To (MM/YY – MM/YY): 03/11 - 07/19
Business Address: 8601 Six Forks Road, Suite 630	City: Raleigh	State: NC	Zip: 27615
Phone: 919-719-6360	Title: Director, Private Investments		
Description of Duties: see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section B: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

SS

Shalin Shah

Original Signature (electronic, copies or stamps not accepted)

10/4/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shalin Shah

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/9/2024

Date

Please have this section completed in the presence of a Notary Public.

State of ~~Shalin Shah~~ Northcarolina, ss. County of Wake County

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Shalin Shah

Original Signature

10/9/2024

Date

Subscribed and Sworn to before me this 9 day of Oct, 2024.

Notary Public Signature

Paula J. Andrews NOTARY PUBLIC Wake County, N.C.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Marius Pharmaceuticals Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH03444

Physical Address 2301 Sugar Bush Road, Suite 510

City Raleigh State NC Zip 27612

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 919-374-1913 Website https://mariuspharma.com/

Licensing Company Email compliance.mariuspharma@gmail.com

Section 2: Personal Information

First Himanshu Middle _____ Last Shah

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Raleigh State NC Zip 27614

Telephone [redacted] Email compliance.mariuspharma@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Akron		08/88 - 12/90	
Address	**City**	**State**	**Zip**
302 E Buchtel Ave	Akron	OH	44325
Diploma/Degree obtained, if any			
MBA Finance & Marketing			
School Name		**From - To (MM/YY – MM/YY)**	
Gajarat University		07/84 - 06/87	
Address	**City**	**State**	**Zip**
	Ahmedabad, India		India
Diploma/Degree obtained, if any			
Accounting & Finance			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/09 - Current	[redacted]	Raleigh	NC	27614
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Marius Pharmaceuticals Inc			01/17 - Current	
Business Address	**City**		**State**	**Zip**
2301 Sugar Bush Road, Suite 510	Raleigh		NC	27612
Phone	**Title**			
919-374-1913	Chairman of the Board			
Description of Duties				
see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Shah Capital			01/05 - Current	
Business Address	**City**		**State**	**Zip**
8601 Six Fork Road, Suite 630	Raleigh		NC	27615
Phone	**Title**			
919-719-6360	Founder, President			
Description of Duties				
Owner, CIO				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Himanshu Shah

Original Signature (electronic, copies or stamps not accepted)

10/15/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Himanshu Shah

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/24

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake County

I, Himanshu Shah, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Himanshu Shah

Original Signature

10/15/24

Date

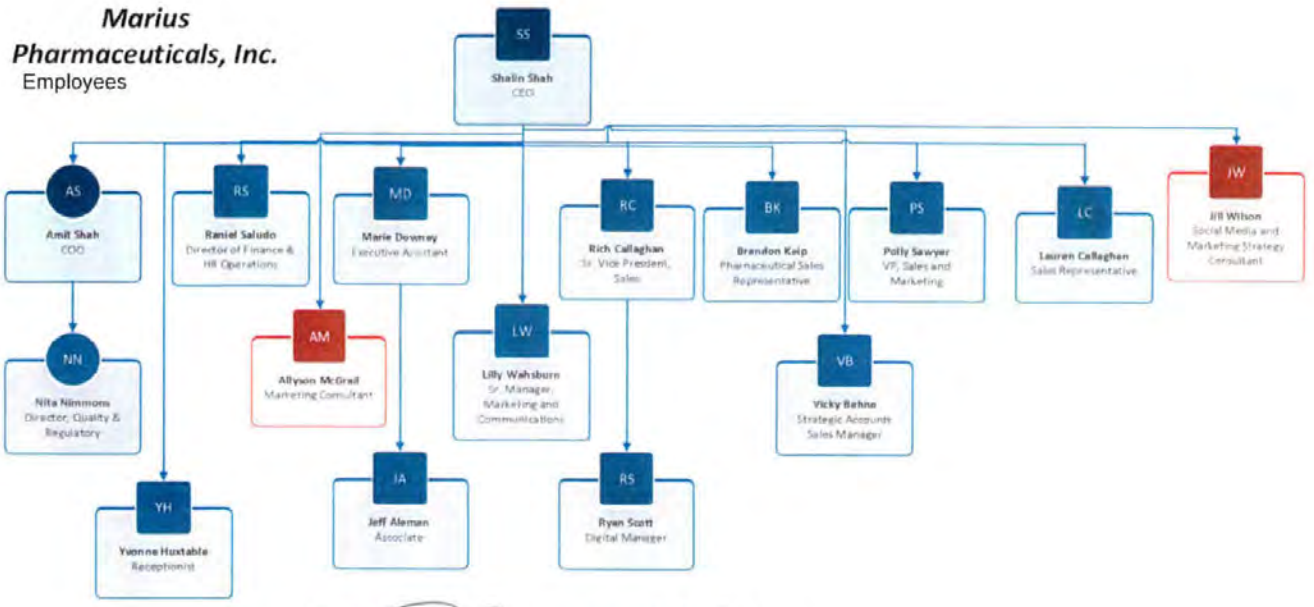
Subscribed and Sworn to before me this 15 day of Oct, 2024

Paula J. Andrews

Notary Public Signature

Paula J. Andrews NOTARY PUBLIC Wake County, N.C.

(Seal)



Approved By/Date: Nita Nimmons
19 Nov 2024

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH MP01168	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Matheson Tri-Gas, Inc.

Physical Address: 5555 District Boulevard

City: Vernon State: CA Zip: 90058

Mailing Address (if different from physical address): 909 Lake Carolyn Pkwy, Suite 1100 (medical licensing)

City: Irving State: TX Zip: 75039

Telephone: 972-560-5699 Website: www.mathesongas.com

Name of Designated Representative (DR): Mark Schinaman

Licensing Company Email: Licensing@mathesongas.com DR Email: mschinaman@mathesongas.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Matheson Tri-Gas, Inc.
Address: Corp: 909 Lake Carolyn Pkwy, Ste 1300 City: Irving State: TX Zip: 75039
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Nippon Sanso Holdings Corporation
Corporation/Organization Name: Malheson Tri-Gas, Inc
Mailing Address: 909 Lake Carolyn Pkwy, Suite 1100
City: Irving State: TX Zip: 75039
Telephone: 484-919-7129 Email: mcelii@mathesongas.com
Contact Person Name: Mark Celii

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Vernon Co

Facility Name

Mark Celi

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/14/24

Date

Board Use Only	Date Received: 10/24/24	Amount: $475 ck 1443446

Certificate of Compliance

Record of FDA Electronic Registration as

Drug Manufacturer

for

Firm Name	Facility Establishment Number	Data Universal Numbering System Number	Address	Expiration Date
Matheson Tri-Gas, Inc.	3006376135	965758985	5555 District Boulevard Vernon, CA 90058	12 / 31 / 2024

This certificate indicates that Matheson Tri-Gas has registered with the FDA as a Drug Establishment which expires 31 December 2024.

MATHESON

The Gas Professionals

MATHESON TRI-GAS, INC.
CORPORATE OFFICERS
2024

State of Incorporation: Delaware – March 1987
Matheson Tri-Gas, Inc. owns 100% of the company shares
Tax ID: 74-2460354

Thomas S. Kallman, Chairman & CEO
Office: 909 Lake Carolyn Pkwy, Suite 1300
Irving, TX 75039
Phone: 972-560-5706

Kelvin Dixon, Sr. VP Risk Management
Office: 3 Mountainview Rd.
Warren, NJ 75039
Phone: 908-991-9333

Stephen Stroud, EVP General Counsel/Secretary
Office: 3 Mountainview Rd.
Warren, NJ 75039
Phone: 908-991-9333

NIPPON SANSO HOLDINGS

Status of major shareholders

As of March 31, 2024

(Top 10 shareholders, number of shares rounded down to the nearest 1,000)

	Shares held (share/1000)	Shares held (%)
Mitsubishi Chemical Group Corporation	218,996	50.59
The Master Trust Bank of Japan, Ltd. (trust account)	29,632	6.85
Client shareholding association of Taiyo Nippon Sanso Corporation	16,706	3.86
Custody Bank of Japan, Ltd. (trust account)	11,422	2.64
Meiji Yasuda Life Insurance Company	9,006	2.08
Mizuho Bank, Ltd.	4,332	1.00
THE BANK OF NEW YORK MELLON 140044	3,393	0.78
State Street Bank West Client – Treaty 505234	3,179	0.73
Ibiden Co., Ltd.	3,004	0.69
JP MORGAN CHASE BANK 385632	2,806	0.65

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MATHESON TRI-GAS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MATHESON TRI-GAS, INC." WAS INCORPORATED ON THE TWELFTH DAY OF MARCH, A.D. 1987.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





2120313 8300

SR# 20243830717

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204530621

Date: 10-01-24

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DRUG MANUFACTURING LICENSE

Matheson Tri-Gas, Inc.
5555 District Blvd
Vernon, CA 90058

LICENSE NUMBER: 47043
EXPIRATION DATE: 5/18/2026

The person named herein is licensed to manufacture drugs through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

OSP 07 102308

Printed: 5/2/2024

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/18/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
INSURED Matheson Tri-Gas, Inc. 3 Mountainview Road, 3rd Floor Warren, NJ 07059	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: Tokio Marine Specialty Insurance Company 23850 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W36265210 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GLS 4300661-01	12/01/2023	12/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG SIR	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 10,000,000 $ 5,000,000 $ 2,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: 5555 District Boulevard in Vernon CA.

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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SR ID: 26785179 BATCH: 3709013

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 72461822

Application/License No. _____

Matheson Tri-Gas, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
5555 District Boulevard, Vernon, CA 90058, as
Address of Applicant/Principal
PRINCIPAL, and Western Surety Company, a
Surety Company
corporation organized under the laws of the state of SD
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
151 N. Franklin Street , Chicago, IL 60606 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 12, 2022.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 12th day of May, 2022.

APPLICANT/PRINCIPAL

Matheson Tri-Gas, Inc.

By: _____
Authorized Representative
Stephen T. Stroud

SURETY COMPANY

Western Surety Company

By: _____
Surety Company's Representative

Wendy Lee Wadkins, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness Kristine Jordan

_____
Witness Chris Kay

SIGNED and SEALED in the presence of:

_____
Witness Pablo Rios, Jr.

_____
Witness Robyn Meier

Countersigned by:

_____
Nevada Resident Agent Wendy Lee Wadkins, NV Non-Resident License #3091632

Posted February 20, 2020

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2021

ASSETS

Bonds	$	1,940,298,870
Stocks		19,721,943
Cash, cash equivalents, and short-term investments		32,146,891
Receivables for securities		140,000
Investment income due and accrued		17,433,547
Premiums and considerations		54,366,110
Amounts recoverable from reinsurers		3,204,634
Current federal and foreign income tax recoverable and interest thereon		-
Net deferred tax asset		14,565,007
Receivable from parent, subsidiaries, and affiliates		14,891,869
Other assets		1,037
Total Assets	$	2,096,769,908

LIABILITIES AND SURPLUS

Losses	$	214,859,103
Loss adjustment expense		48,667,258
Commissions payable, contingent commissions and other similar charges		10,885,216
Other expenses (excluding taxes, license and fees		-
Taxes, License and fees (excluding federal and foreign income taxes)		2,781,662
Federal and foreign income taxes payable		300,285
Unearned premiums		263,317,295
Advance premiums		6,618,279
Ceded reinsurance premiums payable (net of ceding commissions)		5,081,348
Amounts withheld or retained by company for account of other		10,237,011
Provision for reinsurance		6,261,560
Payable to parent, subsidiaries and affiliates		7,170
Payable on security transactions		35,226
Other liabilities		155,189
Total Liabilities	$	569,206,602

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,236,667,111		
Surplus as regards policyholders		$	1,527,563,306
Total Liabilities and Capital		$	2,096,769,908

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Wendy Lee Wadkins, Individually

of, Radnor, PA , its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

Surety Bond No.: 72461822
Principal: Matheson Tri-Gas, Inc.
Obligee: Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 16th day of June, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 16th day of June, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 12th day of May, 2022.

WESTERN SURETY COMPANY

L. Nelson, Assistant Secretary

Form F4280-7-2012

Go to www.cnasurety.com > Owner / Obligee Services > Validate Bond Coverage, if you want to verify bond authenticity.

Authorizing By-Law

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Matheson Tri-Gas, Inc. MDEG License # (if applicable): MP01168

Physical Address: 5555 District Boulevard

City: Vernon State: CA Zip: 90058

Mailing Address (if different from physical address): 909 Lake Carolyn Parkway, Suite 1100 (Medical Licensing)

City: Irving State: TX Zip: 75039

Telephone: 800-416-2505 Website: www.mathesongas.com

Licensing Company Email: licensing@mathesongas.com

Section 2: Personal Information

First: Mark Middle: Anthony Last: Schinaman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 5555 District Blvd

City: Vernon State: CA Zip: 90058

Telephone: [redacted] Email: mschinaman@mathesongas.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aiken High School		8/2000 - 6/2001	
Address	**City**	**State**	**Zip**
5641 Belmont Ave	Cincinnati	OH	95224
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2021 - Current	[redacted]	Upland	CA	91784
From - To (MM/YY – MM/YY)		City	State	Zip
12/2012 - 6/2021		Covina	CA	91723
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Matheson Tri-Gas			12/2012 - Current	
Business Address		City	State	Zip
5555 District Blvd		Vernon	CA	90058
Phone	Title		Number of Employed Hours	
323-773-0159	Plant Manager / Regional Operations Manag		>20,000 hrs	
Description of Duties				
Day to day operational management; production management, personnel management, compliance management, safety management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Mark Schinaman, **certify that as the MDEG Administrator for**

Matheson Tri-Gas, Inc.,

that I (initial that you have read and meet the following requirements):

1. MAS Have a high school diploma or its equivalent;
2. MAS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MAS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MAS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Schinaman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/2/2024
Date

Board Use Only	Date Received: 10/24/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Matheson Tri-Gas, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5555 District Boulevard

City: Vernon State: CA Zip: 90058

Mailing Address (if different from physical address): 909 Lake Carolyn Parkway, Suite 1100 (Medical Licensing)

City: Irving State: TX Zip: 75039

Telephone: 800-416-2505 Website: 909 Lake Carolyn Parkway, Suite 1100 (Medical Licensing)

Licensing Company Email: licensing@mathesongas.com

Section 2: Personal Information

First: Mark Middle: Anthony Last: Schinaman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 5555 District Blvd.

City: Vernon State: CA Zip: 90058

Telephone: [redacted] Email: mschinaman@mathesongas.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aiken High School		8/2000 - 6/2001	
Address	**City**	**State**	**Zip**
5641 Belmont Ave	Cincinnati	OH	45224
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2021- Current	[redacted]	Upland	CA	91784
12/2012 - 6/2021		Covina	CA	91723
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Matheson Tri-Gas			12/2012 - Current	
Business Address		**City**	**State**	**Zip**
5555 District Blvd.		Vernon	CA	90058
Phone	**Title**		**Number of Employed Hours**	
323-773-0159	Plant Manager / Regional Operations Manager		>20,000 hrs	
Description of Duties				
Day to day operational management; production management, personnel management, compliance management, safety management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Mark Schinaman, certify that as the designated representative for Matheson Tri-Gas, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MAS I am at least 21 years of age;
3. MAS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MAS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MAS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MAS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MAS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mark Schinaman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-15-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Schinaman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/2/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Mark Schinaman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-9-24

Date

Subscribed and Sworn to before me this 9th day of October 2024

Notary Public Signature

JOHN M. TRUJILLO
COMM. #2358587
Notary Public - California
Los Angeles County
My Comm. Expires May 23, 2025

NRO1 NRO1

(Seal)

Matheson Tri-Gas Inc.

List of employees - Vernon, CA

Juan Moran
Jeremy Aguirre
Richard Quizon
James Englert
Mark Schinaman
Matthew Mehaffey

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Neurotech Pharmaceuticals Inc.

Physical Address: 900 Highland Corporate Drive, Building 1

City: Cumberland State: RI Zip: 02864

Mailing Address (if different from physical address): 900 Highland Corporate Drive, Suite 101

City: Cumberland State: RI Zip: 02864

Telephone: 401-333-3880 Website: https://www.neurotechpharmaceuticals.com/about-us/

Name of Designated Representative (DR): Scott Hunter

Licensing Company Email: statelicensure@neurotechusa.com DR Email: s.hunter@neurotechusa.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Specialty Pharmacies		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-12-2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Neurotech Holdings, LLC

Corporation/Organization Name: Neurotech Pharmaceuticals, Inc.

Mailing Address: 900 Highland Corporate Drive, Suite 101

City: Cumberland State: RI Zip: 02864

Telephone: 862-812-6437 Email: statelicensure@neurotechusa.com

Contact Person Name: Scott Hunter

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• ***Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing *Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Neurotech Pharmaceuticals Inc.
Facility Name

Scott Hunter
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-12-2024
Date

Board Use Only	Date Received: 9/12/24	Amount: $1000-CK 2639 ✓

An official website of the United States government Here's how you know

FDA

Home Drug Databases DECRS Search Result

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Drug Establishments Current Registration Site

New Search

Search Results for *Neurotech*

Showing 1 to 1 of 1 entries Show entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Neurotech Pharmaceuticals, Inc.	3012545799	117685116	MANUFACTURE	900 Highland Corporate Drive Building 1 Ste 101, Cumberland, Rhode Island (RI) 02864, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Oct 30, 2024

New Search

neurotech

Company Information

Company Name: Neurotech Pharmaceuticals Inc.
Address: 900 Highland Corporate Drive, Building 1
City, State, Zip: Cumberland, RI 02864
Phone: (401) 333-3880
Website: www.neurotechpharmaceuticals.com
E-mail: statelicensure@neurotechusa.com

FEIN: 52-2397166
State of Formation: DE
Date Incorporated: 05/31/2006

Ownership Information

Neurotech is owned by Neurotech Holdings, LLC
Parent Company Address: 900 Highland Corporate Drive, Building 1, Cumberland, RI 02864
Parent Company Phone: (401) 333-3880

Officers

Richard Small, Chief Executive Officer
Business Address: 900 Highland Corporate Drive, Suite 101, Cumberland, RI 02864
Business Phone: (401) 333-3880

Scott Hunter, Chief Commercial Officer
Business Address: 900 Highland Corporate Drive, Suite 101, Cumberland, RI 02864
Business Phone: (401) 333-3880

neurotech

DESCRIPTION OF OPERATIONS

Manufacturing Information

Neurotech Pharmaceuticals Inc. ("Neurotech") manufactures their products (Labeler 82958), at its facility located at:

Neurotech Pharmaceuticals Inc.
900 Highland Corporate Drive, Building 1
Cumberland, RI 02864
P: (401) 333-3880
Hours of Operations: 8:00 a.m. – 5:00 p.m. EST, Monday-Friday.
FDA Establishment Number: 3012545799

Third-Party Logistics Information

Neurotech will utilize ICS as the Third-Party Logistics provider to manage the storage and distribution of Neurotech's products to Hospital Pharmacies, Specialty Distributors, and Specialty Pharmacies. ICS is located at:

Integrated Commercialization Solutions, Inc. (ICS)
420 International Blvd.
Suite 500
Brooks, KY 40109

Facility Information

Neurotech has 72 employees working on site during normal business hours

Neurotech's hours of operation are 9:00 am – 5:00pm Monday through Friday

Neurotech's records are stored at both Neurotech and ICS

Neurotech's facility square footage is 27,000

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NEUROTECH PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NEUROTECH PHARMACEUTICALS, INC." WAS INCORPORATED ON THE THIRTY-FIRST DAY OF MAY, A.D. 2006.

Jeffrey W. Bullock, Secretary of State

4167199 8300

SR# 20243155291

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204167824

Date: 08-15-24

State of Rhode Island
Department of Health

RHODE ISLAND BOARD OF PHARMACY

This is to certify that NEUROTECH PHARMACEUTICALS, INC. located at 900 HIGHLAND CORPORATE DR, BUILDING 1, CUMBERLAND RI 02864, having given satisfactory evidence that said agency is qualified in conformity with Chapter 5-19 of the General Laws of 1956, as amended, is hereby granted a license to operate as a

Drug Manufacturer-In State

in the State of Rhode Island, for the period ending: **09/30/2025**

License Number: ***MNF00179***

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800024424

Application/License No. _____

Neurotech Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 900 Highland Corporate Drive, Building 1, Cumberland, RI 02864 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800 , Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 26, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of June, 2024.

APPLICANT/PRINCIPAL

Neurotech Pharmaceuticals, Inc.

By: _____
Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

By: _____
Surety Company's Representative

Craig H. Meeker, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Nicole Plourde

_____
Witness Casey Baez

Countersigned by:

_____
Nevada Resident Agent n/a

Posted February 20, 2020

[intact] INSURANCE

Power of Attorney

Surety Bond No: 800024424

Principal: Neurotech Pharmaceuticals, Inc.
Obligee: Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: Craig H. Meeker, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **sixty million dollars ($60,000,000)** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this fifth day of March, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this fifth day of March, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2026

_____
Notary Public

I, the undersigned, Assistant Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 26th day of June, 2024.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Christopher V. Jerry, Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Neurotech Pharmaceuticals Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 900 Highland Corporate Drive, Building 1

City Cumberland State RI Zip 02864

Mailing Address (if different from physical address) 900 Highland Corporate Drive, Suite 101

City Cumberland State RI Zip 02864

Telephone 401-333-3880 Website https://www.neurotechpharmaceuticals.com/about-us/

Licensing Company Email statelicensure@neurotechusa.com

Section 2: Personal Information

First Scott Middle _____ Last Hunter

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 900 Highland Corporate Drive, Building 1

City Cumberland State RI Zip 02864

Telephone 401-333-3880 Email s.hunter@neurotechusa.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Gaither High School		09/92 – 05/93	
Address	**City**	**State**	**Zip**
6200 N Dale Mabry Hwy	Tampa	FL	33618
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		09/94 - 05/99	
Address	**City**	**State**	**Zip**
4202 E Fowler Ave	Tampa	FL	33620
Diploma/Degree obtained, if any			
Bachelors of Science - Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23 - Present	[redacted]	Boston	MA	02116
From - To (MM/YY – MM/YY)		City	State	Zip
01/23 - 11/23		Boston	MA	02116
From - To (MM/YY – MM/YY)		City	State	Zip
04/21 - 12/22		Basel	Switzerl	4051
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Neurotech Pharmaceuticals Inc.			01/23 - Present
Business Address	**City**	**State**	**Zip**
900 Highland Corporate Drive, Building 1	Cumberland	RI	02864
Phone	**Title**	**Number of Employed Hours**	
401-333-3880	Chief Commercial Officer	1640+	
Description of Duties			
See Attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Novartis Pharma Services			05/19 - 12/22
Business Address	**City**	**State**	**Zip**
Lichtstrasse 35	Basel	Switzerla	CH-4056
Phone	**Title**	**Number of Employed Hours**	
+41 61 324 00 00	Global Marketing Executive Director	6000+	
Description of Duties			
See Attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

SCOTT HUNTER

[redacted] • Boston, MA 02116 • 862-812-6437 • S.Hunter@neurotechusa.com

Highly strategic leader with significant experience leading and inspiring global cross-functional teams to successfully launch new products and quickly drive revenue generation. Agility to operate in a global environment with demonstrated knowledge of key markets. Deep experience in the ophthalmology space with strong key opinion leader (KOL) relationships and special expertise in the commercialization of ophthalmic products. Ability to dive into complicated, decentralized processes and projects while quickly grasping the big picture.

Strategy Development and Implementation / Forecasting and Planning / KOL Advocacy
Product Launch / Market Access / In-Line Marketing / Campaign Development

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NEUROTECH PHARMACEUTICALS – Cumberland, Rhode Island 2023 – PRESENT

Chief Commercial Officer
Hired in January 2023 as the companies first CCO leading the commercialization of NT-501

NOVARTIS – Basel, Switzerland 2019 – 2022

Global Marketing Executive Director (2019 –Present)
Joined Novartis as part of Xiidra acquisition. Following integration of Xiidra I continued with the organization to lead Luxturna global marketing team.

Direct Reports: 0 – 3 | **Budget:** $2 – $12 million | **Revenues:** $75 – $430 million

Gene Therapy:

- **Accelerated Growth:** More than doubled the number of patients treated in 2021 over the prior year through expanded access (9 new countries reimbursed in 2021) and increased patient identification.
- **Launch Preparation:** Led cross-functional team responsible for partnering with local affiliates to ensure launch readiness: including - pricing model, patient and policy advocacy, supply chain set-up and treatment site certification

TAKEDA (FORMERLY SHIRE OPHALMOLOGY) – Boston, MA and Zug, Switzerland 2014 – 2019

Interim Global Product Strategy Lead (Functioning at a Vice President Level) (2018 –2019)
Senior Director, Global Commercial Lead (2016 – 2018)
Director, U.S. HCP Marketing (2014 – 2016)
Recruited to Shire by the Senior Vice President of U.S. Commercial to build the Ophthalmology Franchise and commercialize the company's foundational pipeline product (Xiidra). Based on the successful U.S. launch, tapped by senior leadership to move to Switzerland to lead global expansion and life cycle management.

Direct Reports: 1 – 7 | **Budget:** $12 – 52 million | **Revenues:** $0 – $389 million

Establishment of Shire U.S. Ophthalmology Franchise:

- **Strategic Planning:** Partnered with U.S. Business Unit Head to develop and communicate Shire's long-term ophthalmology strategy, resulting in two strategic acquisitions and the successful U.S. launch of Xiidra.
- **Organization Ramp-up:** A key leader and member of team responsible for building the Ophthalmology Franchise from a team of 2 in the U.S. to a team of 450+ globally. Hired U.S. marketing team and collaborated with head of sales to build territory structures and to hire/train 300+ reps and managers.

Xiidra U.S. Launch

- **Launch Readiness:** Led the development of Xiidra launch plan and long-term forecast. Co-created Xiidra brand campaigns (Professional & Consumer), market development activities, and generation of customer insights resulting in strong brand differentiation clearly filling an unmet need.
- **Strategic Execution:** Guided successful launch of Xiidra resulting in 90% brand awareness among targets 3-months post-launch and 46% new to brand share at 9-months post-launch.
- **Patient Support and Access:** Built and deployed extensive patient support program with Market Access team, including a first in class patient hub to help patients clarify benefits and navigate coverage gaps. In first year received over 150,000 inbound calls and completed 55,000 benefits investigations.

Global Product Strategy

- **Cross-Functional Leadership:** Led the Late Phase Team (LPT), driving Xiidra's long-term strategy across all functions (i.e. Medical Affairs, Regulatory, and Access). Results included 10 MA approvals to date, Centralized EMA submission, global pricing and access plan, and a China business case endorsed by Executive Committee.

- **Global Expansion:** Managed global team supporting 15 priority launch countries with localization and implementation, including recruitment of local teams, label negotiations, creation of tactical plans and reimbursement. Successfully launched first country (Canada) with year one sales at 187% to plan.
- **Life-Cycle Management:** Provided strategic leadership to Xiidra LPT for the development of life cycle plan intended to optimize asset value.
- **BD&L:** Member of core team tasked with divestiture of ophthalmology franchise leading to sale of Xiidra to Novartis for $3.4 billion. Responsibilities included participation in management presentations to prospective bidders, coordinating responses to due diligence requests, and integration planning.

Organizational Leadership

- **Cross-Cultural Leadership:** Led geographically dispersed cross-functional teams (15+) to collaborate and to communicate effectively under tight timelines.
- **Staff Coaching & Mentoring:** Mentored direct reports and junior colleagues on their career development leading to several staff accepting roles of increased responsibility.

BAUSCH HEALTH (FORMERLY BAUSCH + LOMB) – Madison, NJ and Tampa, FL 2002 – 2014

Director, Anti-inflammatory (2013 – 2014)
Senior Product Manager, Lotemax (2011 – 2013)
Product Manager, Allergy (2009 – 2010)
Associate Product Manager, Digital Promotion (2008 – 2009)

Promoted through increasingly responsible roles across in-line brand management and product launches within a mid-sized organization, providing exposure to all aspects of the business. Started career in R&D before moving into a commercial role. Consistent results growing in-line brands led to the opportunity to lead 3 successful product launches.

Direct Reports: 1 – 4 | **Budget:** $5 – 10 million | **Revenues:** $22 – $236 million

Launch Strategy & Brand Building

- Generated over $230 million in annual revenues by creating comprehensive cross-functional launch plans for Prolensa, Lotemax Gel, and Lotemax Ointment. Developed launch forecast, trade and manage care strategies, and launch KPIs.
- Converted 90% of Bromday business to Prolensa ($75 million) within 6-months of launch by working closely with sales leadership to communicate and execute a focused plan to convert targeted priority accounts.
- Grew Lotemax franchise through effective co-positioning of Lotemax Gel and Lotemax ointment line extensions, resulting in 12% growth of the Lotemax franchise in year 1.

In-Line Brand Management

- Partnered with the external brand agency to develop new positioning and creative campaign for Alrex, resulting in 108% of plan for the year.
- Led the development of all core selling resources including field sales force materials, media plan, peer to peer, and congress activities providing focused and consistent messaging across channels.
- Collaborated with Medical Affairs to develop KOL networks across ophthalmology and optometry by partnering on activities to educate the eye care community and gain customer feedback

Senior Clinical Safety Specialist (2002 – 2008)
Hired to manage global adverse events reporting for pipeline products. Then promoted to lead the team of two for the same activity. Pursued both MBA and M.S. degrees while in role.

- Key contributor on submission teams leading to two NDA approvals (Retisert & Besivance).

EDUCATION AND PROFESSIONAL DEVELOPMENT

Master of Science (M.S.), Pharmacy – UNIVERSITY OF FLORIDA, Gainesville, FL

Master of Business Administration (MBA) – UNIVERSITY OF TAMPA, Tampa, FL

Bachelor of Science (B.S.), Biology – UNIVERSITY OF SOUTH FLORIDA, Tampa, FL

LEAD Certificate in Corporate Innovation, STANFORD GRADUATE SCHOOL OF BUSINESS, 2018 (One-year intensive program)

Chief Marketing Officer Program, NORTHWESTERN KELLOGG SCHOOL OF BUSINESS, (ongoing, completion in 2023)

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

I, Scott Hunter, **certify that as the designated representative for**

Neurotech Pharmaceuticals Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Scott Hunter

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-12-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Hunter

Print Name (First, Last)

S. Hunt

Original Signature (electronic, copies or stamps not accepted)

9-12-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Rhode Island, ss. County of Providence

I, Scott Hunter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

S. Hunt

Original Signature

9-12-2024

Date

Subscribed and Sworn to before me this 12th day of September 2024

Suzanne E. Gaddy

Notary Public Signature

SUZANNE E. GADDY
Notary Public-State of Rhode Island
My Commission Expires
March 04, 2026

(Seal)

Neurotech Pharmaceuticals, Inc.
Employees List
900 Highland Corporate Drive, Building 1

Boahene, Priscilla
Bonin, Allen
Clasby, Aiden
Cortellessa, Crystal
Ghosh, Monideepa
Greer, Rhonda
Lai, David
Sherman, Sandy
Tetreault, Jonathan
Benton, Meaghan
Cambranes, Joel
Cook, Ralph
Poirier, Dawn
Aguiar, Brett
Belhumeur, Patty
Duff, Brian
Ruginski, Max
Bakhtiari, Shadi
Barnett, Derek
Bradley, Michael
Candelario, Jose
Duggan, John
Kelley, Sean
Ledoux, Amy
Legare, Pamela
Lucas, Alexandra
McGinn, Michael
Morra, Vanessa
Muraj, Evald
Ormonde, Andrew
Patterson, Jacob
Petersen, Pariss
Sousa, Julie
Storch, Stephanie
Yates, Gail
Capwell, Shannon
Chaviari, Sophia
Ducy, Jay
Fernandez, Ashley
Fujita, Ross
Fukuda, Felipe
Greenwood, Kaithlyn

Konyeaso, Roy
Lee, Alice
Simonelli, Leslie
Smith, Ron
Tagoe, Emmanuel
Thibodeau, Laura
Baker, Michael
Noblett, David A

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☒ Ownership Change*	WH WH02463	☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Novadoz Pharmaceuticals, LLC

Physical Address: 20 Duke Road, Suite A

City: Piscataway State: NJ Zip: 08854

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: NovadozPharma.com

Name of Designated Representative (DR): Venkatesh Srinivasan

Licensing Company Email: NVD@slsny.com DR Email: venkatesh.s@novadozpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☒ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Human RX	☐ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distributors, Medical Supply Chains		☒ Others: Manufacturer - Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/01/19		KS		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
Case No. 19-497	Kansas Board of Pharmacy

Reason/Charge
Respondent continued to function as a wholesale distributor in KS after a CHOW rendered their license invalid & prior to obtaining new valid registration

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Novadoz Pharmaceuticals, LLC

Provide explanation below:

Please see attached summary

Venkatesh Srinivasan

Original Signature (electronic, copies or stamps not accepted)

4/23/2024

Date

Discipline

Filed By

NOV 1 2019

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 19-497
Novadoz Pharmaceuticals, LLC	)	
	)	
Registration No. 5-110669	)	

SUMMARY ORDER

NOW, on this 1st day of November 2019, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of Novadoz Pharmaceuticals, LLC ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 5-106949 which entitled Respondent to operate as a wholesale distributor in the State of Kansas ("Respondent's Registration").

2. On June 3, 2019, Respondent submitted to the Board application for renewal of their Registration ("Respondent's Renewal"), which was due to expire on June 30, 2019.

3. On June 3, 2019, the Board approved Respondent's Renewal, effective July 1, 2019.

4. On July 3, 2019, two days after Respondent's Renewal became effective, Respondent experienced a change in ownership.

5. On October 8, 2019, the Board received from Respondent a Form BA-05 Distributor Registration Application ("Respondent's Application"), notifying of the July 3rd change in ownership, and applying for new distributor registration under the new ownership.

6. On October 14, 2019, the Board approved Respondent's Application effective immediately, issuing Respondent the new Registration No. 5-110669.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs without first obtaining a registration as a wholesale distributor form the Board.

3. Respondent's Application indicated that Respondent continued to function as a wholesale distributor in the state of Kansas after the July 3, 2019 ownership change rendered their license invalid, and prior to obtaining new valid registration on October 14, 2019.

4. By continuing to operate as a wholesale distributor under an invalid license, Respondent violated K.S.A. 65-1643(c).

ORDER

The Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $500.00. Respondent has 30 days from the date of this order to pay the full $500.00.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

11/1/19
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 1st day of November 2019, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

NOVADOZ PHARMACEUTICALS, LLC
ATTN: SESHU AKULA
20 DUKE RD, STE A
PISCATAWAY, NJ 08854

Kansas Board of Pharmacy Staff

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: CENCORA INC
Address: 1 WEST FIRST AVE City: CONSHOHOCKEN State: PA Zip: 19428
Name: MCKESSON
Address: 6555 STATE HWY 161 City: IRVING State: TX Zip: 75039
Name: CARDINAL HEALTH
Address: 7000 CARDINAL PL City: DUBLIN State: OH Zip: 43017
Name: KAISER PERMANENTE
Address: 2921 NACHES AVE SW BLD-B City: RENTON State: WA Zip: 98057

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ
Parent Company (if any): Manne Sindhuja Reddy (86.54% Ownership) & Bharat Chintapally (13.46% Ownership)
Corporation/Organization Name: Novadoz Pharmaceuticals, LLC
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: NVD@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 72205	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Novadoz Pharmaceuticals, LLC

Facility Name

Venkatesh Srinivasan

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/23/2024

Date

Board Use Only	Date Received: 9/25/24	Amount: $1000-CK 3603

Labeler Code

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through April 12, 2024

You have searched Finished drug products

Search Results: '72205'

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
Abiraterone	72205-030-92	250 mg/1	TABLET	ORAL	ANDA210686	Novadoz Pharmaceuticals LLC	72205-030	Abiraterone acetate	ABIRATERONE ACETATE	HUMAN PRESCRIPTION DRUG	07/10/2019	N/A	ANDA
Acyclovir suspension	72205-170-72	200 mg/5mL	SUSPENSION	ORAL	ANDA217393	Novadoz Pharmaceuticals LLC	72205-170	Acyclovir	ACYCLOVIR	HUMAN PRESCRIPTION DRUG	10/23/2023	N/A	ANDA
Albendazole	72205-051-08	200 mg/1	TABLET	ORAL	ANDA213435	Novadoz Pharmaceuticals LLC	72205-051	Albendazole	ALBENDAZOLE	HUMAN PRESCRIPTION DRUG	02/24/2021	N/A	ANDA
Albendazole	72205-051-28	200 mg/1	TABLET	ORAL	ANDA213435	Novadoz Pharmaceuticals LLC	72205-051	Albendazole	ALBENDAZOLE	HUMAN PRESCRIPTION DRUG	02/24/2021	N/A	ANDA
Aminocaproic acid	72205-049-30	500 mg/1	TABLET	ORAL	ANDA212938	Novadoz Pharmaceuticals LLC	72205-049	Aminocaproic acid	AMINOCAPROIC ACID	HUMAN PRESCRIPTION DRUG	12/10/2020	N/A	ANDA
Aminocaproic acid	72205-286-30	1000 mg/1	TABLET	ORAL	ANDA212938	Novadoz Pharmaceuticals LLC	72205-286	Aminocaproic acid	AMINOCAPROIC ACID	HUMAN PRESCRIPTION DRUG	09/21/2023	N/A	ANDA
ARSENIC TRIOXIDE	72205-171-07	1 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Novadoz Pharmaceuticals LLC	72205-171	ARSENIC TRIOXIDE	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	02/06/2024	N/A	ANDA
ARSENIC TRIOXIDE	72205-172-07	2 mg/2mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Novadoz Pharmaceuticals LLC	72205-172	ARSENIC TRIOXIDE	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	02/06/2024	N/A	ANDA
Atorvastatin calcium	72205-022-99	10 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-022	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	03/24/2022	N/A	ANDA
Atorvastatin calcium	72205-022-05	10 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-022	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-022-30	10 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-022	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-022-90	10 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-022	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-023-05	20 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-023	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-023-30	20 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-023	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-023-90	20 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-023	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA
Atorvastatin calcium	72205-024-05	40 mg/1	TABLET, FILM COATED	ORAL	ANDA211933	Novadoz Pharmaceuticals LLC	72205-024	Atorvastatin calcium	ATORVASTATIN CALCIUM TRIHYDRATE	HUMAN PRESCRIPTION DRUG	02/08/2019	N/A	ANDA

0823

Novadoz Pharmaceuticals, LLC

Corporate Address: 20 Duke Road A, Piscataway, NJ 08854 USA
FEIN: 82-3950757
NovadozPharma.com

Drug Labeler Code: 72205
Incorporation State: NJ
Incorporation Date: 1/8/2018

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
20D	20 Duke Road Suite A Piscataway, NJ 08854 County: Middlesex	N/A	N/A - Uses 3PL DEA	081109687	No	(551) 777-0575	(732) 902-2113

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Venkatesh Srinivasan	[redacted]	CEO		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Bharat Chintapally	[redacted]	Shareholder/Director	13.46		[redacted]		
Manne Sindhuja Reddy		Shareholder/Director	86.54				

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Venkatesh Srinivasan	[redacted]	CEO		[redacted]		
Kondal Reddy Bairy		Associate VP, IP & Regulatory				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Eversana Life Science Services, LLC	4580 S Mendenhall Rd Memphis, TN 38141					

Company Particulars

Incorp Good Standing

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

NOVADOZ PHARMACEUTICALS, LLC
0450229624

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on January 08, 2018.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

Venkatesh Srinivasan
20 DUKE RD.
SUITE A
PISCATAWAY, NJ 08854

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 18th day of September, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 2836027776

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

HS License

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0750438

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

20 DUKE RD, STE A PISCATAWAY, NJ 08854-

Reg. No. 5005442

NOVADOZ PHARMACEUTICALS LLC
20 DUKE RD, STE A
PISCATAWAY, NJ 08854-

ISSUED PURSUANT TO N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

Mackenzie Winne - All Ope... > 77477

Reply | Add note | Forward | Close | Merge | Delete

Overdue

RE: [EXTERNAL] Verification of Licensure

DOH-PHFPP reported via email

Add summary

DOH-PHFPP reported via email

18 days ago (Fri, 11 Sep 2020 at 4:44 PM)

To: "'SLSNYSupport.com'" <help@slsnysupport.com>

Thank you. Due to limited resources, the NJ Department of Health cannot complete license verification forms for other states. Please utilize the online verification system on our webpage: https://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/

Jennifer Steffee | Public Health Representative
NJ Department of Health | Public Health & Food Protection
PO Box 369 | 135 E State St | Trenton, NJ 08625
609.913.5150 | http://nj.gov/health/ceohs

VOL

DEA (3PL)

Registrant Verification For

EVERSANA LIFE SCIENCE SERVICES, LLC

DEA Number:	RD0205333
Expiration Date:	08/31/2025
Additional Company Info:	
Registered Address:	4580 S MENDENHALL RD
City:	MEMPHIS
State:	TN
Zip Code:	38141-6700
Business Activity:	DISTRIBUTOR
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	09/12/2024

Department of Justice
Drug Enforcement Administration
Diversion Control Division

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Letter of Credit
NV

JPMORGAN CHASE BANK, N.A.
TRADE & WORKING CAPITAL
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128
SWIFT: CHASUS33

DATE : 04 Sep 2024

IRREVOCABLE STANDBY LETTER OF CREDIT REFERENCE NO.: NUSCGS054224

TO: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

DEAR SIR/MADAM,

WE HEREBY ISSUE OUR IRREVOCABLE STANDBY LETTER OF CREDIT IN YOUR FAVOR.

BENEFICIARY	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206 RENO, NV 89521 ATTN: EXECUTIVE SECRETARY
ACCOUNT PARTY	:	NOVADOZ PHARMACEUTICALS, LLC 20 DUKE ROAD, SUITE A PISCATAWAY, NEW JERSEY, 08854-3714
DATE OF EXPIRY	:	20-JUL-2025
PLACE OF EXPIRY	:	OUR COUNTER
AMOUNT	:	USD 100,000.00
APPLICABLE RULE	:	ISP LATEST VERSION

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF NOVADOZ PHARMACEUTICALS, LLC, WE JPMORGAN CHASE BANK, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT NO. NUSCGS054224 (CREDIT) IN THE PRINCIPAL SUM OF USD 100,000.00 (ONE HUNDRED THOUSAND AND 00/100 U.S. DOLLARS).

2. WE UNDERSTAND THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE ACCOUNT PARTY/LICENSEE.

3. WE FURTHER UNDERSTAND THAT THIS CREDIT IS INTENDED TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY ACCOUNT PARTY/ LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING ACCOUNT PARTY/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS BELOW.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE BY REGISTERED MAIL, RETURN RECEIPT REQUESTED, OR COURIER.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL SEND THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFOR, AND RETURN THE DOCUMENTS TO THE BOARD.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED IN WHOLE OR IN PART ONLY UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA AND INTERNATIONAL STANDBY PRACTICES, 1998, I.C.C. PUBLICATION NO. 590 ('ISP98'). AS TO THE MATTERS NOT COVERED BY ISP98, SHALL BE SUBJECT TO LAWS OF THE STATE OF NEVADA.

PLEASE ADDRESS ALL CORRESPONDENCE REGARDING THIS STANDBY LETTER OF CREDIT QUOTING OUR REFERENCE NUSCGS054224 TO:
JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LC'S
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS054224 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,

_____
Authorized Signature

ATTACHMENT A CERTIFICATE OF DRAWING
IRREVOCABLE STANDBY LETTER OF CREDIT NO.: NUSCGS054224

TO: JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS 10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. PURSUANT TO NRS 639.515(4), A LAWFUL ORDER IMPOSING FINES AND/ OR COSTS AGAINST THE ACCOUNT PARTY/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. NUSCGS054224 (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF USD-----

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF DRAWING ON THIS DAY OF
_____, 20____

NEVADA STATE BOARD OF PHARMACY
BY:_____
EXECUTIVE SECRETARY

ATTACHMENT B

CERTIFICATE FOR CANCELLATION
IRREVOCABLE STANDBY LETTER OF CREDIT NO.: NUSCGS054224 TO: JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS 10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED, OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPRIATE.

2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE# REFERENCED CREDIT.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF CANCELLATION ON THIS DAY OF_____, 20_

NEVADA STATE BOARD OF PHARMACY
BY: _____
EXECUTIVE SECRETARY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Novadoz Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable): WH02463

Physical Address: 20 Duke Road, Suite A

City: Piscataway State: NJ Zip: 08854

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: NovadozPharma.com

Licensing Company Email: NVD@slsny.com

Section 2: Personal Information

First: Venkatesh Middle: Last: Srinivasan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Livingston State: NJ Zip: 07039

Telephone: [redacted] Email: venkatesh.s@novadozpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Indian Institute of Management		Graduated 03/97	
Address	City	State	Zip
Ahmedabad, India			
Diploma/Degree obtained, if any			
Masters in Business Administration (PGDM)			

School Name		From - To (MM/YY – MM/YY)	
Washington State University		Graduated 03/90	
Address	City	State	Zip
255 E Main St	Pullman	WA	99163
Diploma/Degree obtained, if any			
Master of Science, Chemical Engineering (M.S.)			

School Name		From - To (MM/YY – MM/YY)	
University of Mumbai		Graduated 05/88	
Address	City	~~State~~	~~Zip~~
Mahatma Gandhi Road, Mantralaya, Fort, Mumbai,	Maharashtra, 400032,	India	
Diploma/Degree obtained, if any			
Bachelor of Chemical Engineering, U.D.C.T. (B. Chem. Eng.)			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MUMBAI, DEPARTMENT OF CHEMICAL ENGG.		06/1984 - 05/1988	
Address	City	State	Zip
N.P. MARG, MATUNGA EAST	MUMBAI	MAHARASHTRA	400019
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2016 - Present	[redacted]	Livingston	NJ	07039
12/2014 - 07/2016		Tenafly	NJ	07670
2011 - 11/2014		Mumbai - 400053	~~State~~ India	~~Zip~~
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Novadoz Pharmaceuticals, LLC			09/22 - Present	
Business Address		**City**	**State**	**Zip**
20 Duke Road, Suite A		Piscataway	NJ	08854
Phone	**Title**		**Number of Employed Hours**	
(551) 777-0575	CEO		~ 3,291 Hours	

Description of Duties
Responsible for executing the long-term sustainable strategy for MSN operations in the US. Own all aspects of the business that lead to growth, profitability, and cash flows. Drive the commercial strategies and business development initiatives for Novadoz to achieve planned outcomes. Responsible for interacting and managing the Eversana 3PL operations including existing volumes and future new product launches. This also includes ensuring regulatory compliance and customer service levels.

Business Name			From - To (MM/YY – MM/YY)	
Strides Pharma Inc.			05/22 - 07/22	
Business Address		**City**	**State**	**Zip**
2 Tower Center Blvd #1102		East Brunswick	NJ	08816
Phone	**Title**		**Number of Employed Hours**	
(609) 773-5000	President		~ 346 Hours	

Description of Duties
Role involved managing the front end operations including sales operations and oversight of the manufacturing operations in Chestnut Ridge, NY and also manage 3PL operations.

Business Name			From - To (MM/YY – MM/YY)	
Micro Labs USA Inc.			01/21 - 05/22	
Business Address		**City**	**State**	**Zip**
104 Carnegie Center Dr		Princeton	NJ	08540
Phone	**Title**		**Number of Employed Hours**	
(908) 484-7410	President		~ 2760	

Description of Duties
Responsible for managing the operations and delivering the financial goals for the organization. Achieved ~ 42% growth to deliver $72m revenues and $12 m EBITDA (end March 2022).Delivered 4 BD deals which will deliver ~ 10% of revenues in 2022. Managed interactions and responsible for 3PL operations and compliance.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Venkatesh Srinivasan, **certify that as the designated representative for**

Novadoz Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VS I am at least 21 years of age;
3. VS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Venkatesh Srinivasan
Print Name (First, Last)

Venkatesh S
Original Signature (electronic, copies or stamps not accepted)

4/23/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Venkatesh Srinivasan

Print Name (First, Last)

Venkatesh

Original Signature (electronic, copies or stamps not accepted)

4/24/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Middlesex

I, Venkatesh Srinivasan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Venkatesh

Original Signature Venkatesh Srinivasan

4/24/2024

Date

Subscribed and Sworn to before me this 24th day of April.

Notary Public Signature

ADELFA VICTORIANO NOTARY PUBLIC ID # 50074321 COMMISSION EXPIRES 01/08/28 STATE OF NEW JERSEY

(Seal)

Employee List

Employee Name	Designation
Venkatesh Srinivasan	CEO
Janet Bell	Director-National Accounts
Sherice Koonce	Sr. Director, Pricing & Contracts
Neema Daniels	Manager, Customer Service
Anne Sather	Sr.Director-National Accounts
Brianna Johnson	Customer Service Lead
Siddhi Patel	converted to SC Analyst 2/1/24
Adelfa Victoriano	Manager, Sales Ops
Vinita Singh	Supply Planning Analyst
Priscilla Handley	National Accounts Manager
Matthew Schank	Manager, Pricing & Contracts
Vignesh Nagarajan	Director, Supply Chain Ops
Robert Summer-Brason	Sr. Mgr, Pricing & Contracts
Andres Castano	Sr. Analyst, Pricing & Contracts
Adrian Brieger	Manager, Financial Ops
Kushana Bailey	Sr. Analyst, Financial Ops
Eunice Pelaez	Temp, Customer Service
Atharva Patil	Supply Chain Analyst

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Novadoz Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 20 Duke Road, Suite A

City: Piscataway State: NJ Zip: 08854

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: NovadozPharma.com

Licensing Company Email: NVD@slsny.com

Section 2: Personal Information

First: Bharat Middle: Last: Chintapally

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Telangana ~~State~~: India ~~Zip~~:

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

M. SADA SIVA KUMAR REDDY ADVOCATE ★ NOTARY Regn No 198 ★ F-102, SARASWATHI ENCLAVE BHAGYANAGAR COLONY ★ KUKATPALLY, HYDERABAD, TS, INDIA ★

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: UF, Gainesville			From - To (MM/YY – MM/YY): 8/2003 – 12/2005	
Address: Gainesville, FL	City: FL		State: US	Zip: 32611
Diploma/Degree obtained, if any: MBA				
School Name: FAU — —			From - To (MM/YY – MM/YY): 8/95 – 12/96	
Address: 777 Glades Rd, Boca Raton	City: BOCA		State: US	Zip: 33431
Diploma/Degree obtained, if any: M.S/CS				
School Name: Clemson Uni			From - To (MM/YY – MM/YY): 8/92 – 12/94	
Address: Clemson, South Carolina	City: Clem		State: US	Zip: 29634
Diploma/Degree obtained, if any: MS.				
School Name: A. N4 Ranga			From - To (MM/YY – MM/YY): 8/87 – 12/91	
Address: Guntur	City: Guntur		State: A.P	Zip: 522034
Diploma/Degree obtained, if any:				
School Name: New Model			From - To (MM/YY – MM/YY): 8/84 – 8/86	
Address: Doodhbowli Road, Kabutar Khana	City: Hyd		State: TN	Zip: 500264
Diploma/Degree obtained, if any:				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2015 – Till date	[redacted]	Hyd	Telangana	500033
1/2006 – 2015		Hyd	Telangana	500038
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

M. SADA SIVA KUMAR REDDY ADVOCATE ★ AJANTA SWATHI ENCLAVE, BHAGYANAGAR COLONY ★ KUKATPALLY, HYDERABAD, T.S. INDIA ★ F-102 ★ NOTARY Regn No 198

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Novadoz Pharmaceuticals, LLC			From - To (MM/YY – MM/YY): 01/2008 - Present
Business Address: 20 Duke Road, Suite A	City: Piscataway	State: NJ	Zip: 08854
Phone: (551) 777-0575	Title: Shareholder/Director (13.49% ownership)		
Description of Duties: As an Executive Director I play a decisive role in Novdoz Pharmaceuticals operations and sales + marketing. I manage all aspects of the organization's critical Business Affairs including Formulation Marketing + Business Development			

Business Name: MSN Group			From - To (MM/YY – MM/YY): 2006 to till date
Business Address: Kondapur, whitefields	City: Hydeabad	State: TS	Zip: 500084
Phone: 040 3043 8699	Title: Executive Director		
Description of Duties: Business development group of the FD business for the Global markets			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

M. SIVA KUMAR REDDY ADVOCATE ★ SARASWATHI ENCLAVE, BHAGYANAGAR COLONY ★ INDIA ★ F-102, KUKATPALLY, HYDERABAD, TS ★ NOTARY Regn No 198

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
F-102, KUKATPALLY, HYDERABAD, TS, INDIA
NOTARY
Regn No 198

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD, TS, INDIA
F-102
NOTARY
Regn No 198

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE BHAGYANAGAR COLONY
KUKATPALLY HYDERABAD. TS INDIA
F-102
NOTARY
Regn No 198

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bharat Chintapally

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2 May 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Telangana, ss. County of India

I, Bharat Chintapally, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2 May 2024

Date

Subscribed and Sworn to before me this 4th day of May '24.

Notary Public Signature

ATTESTED

M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
02, Saraswathi Enclave, Bhagyanagar Colony,
Kaipally, Hyderabad, TS India (Ph:98480 44395

M. SADA SIVA KUMAR REDDY, ADVOCATE, F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, KUKATPALLY, HYDERABAD, INDIA
NOTARY
Regn. No. 198
NOTARIAL

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Novadoz Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 20 Duke Road, Suite A

City: Piscataway State: NJ Zip: 08854

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: NovadozPharma.com

Licensing Company Email: NVD@slsny.com

Section 2: Personal Information

First: Manne Middle: Sindhuja Last: Reddy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: N/A Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: Telangana State: India Zip:

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

M. SADA SIVA KUMAR REDDY ADVOCATE
NOTARY
Regn No 198
F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, KUKATPALLY, HYDERABAD, T.S. INDIA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ISB			6/2017 – 6/2019	
Address	City		State	Zip
Gachibowli	Hyderabad		TS	500111
Diploma/Degree obtained, if any				
MBA				
School Name			From - To (MM/YY – MM/YY)	
JNTU			8/2013 – 8/2015	
Address	City		State	Zip
Kukatpally	Hyderabad		TS	500085
Diploma/Degree obtained, if any				
M. Tech				
School Name			From - To (MM/YY – MM/YY)	
CBIT			8/2008 – 8/2012	
Address	City		State	Zip
Gandipet	Hyderabad		TS	500075
Diploma/Degree obtained, if any				
B. Tech				
School Name			From - To (MM/YY – MM/YY)	
Kakatiya Junior College			6/2006 – 6/2008	
Address	City		State	Zip
SR NAGAR	Hyderabad		TS	500038
Diploma/Degree obtained, if any				
12th Grade				
School Name			From - To (MM/YY – MM/YY)	
HPS			5/2006 – 5/2006	
Address	City		State	Zip
Begumpet	Hyderabad			
Diploma/Degree obtained, if any				
10th Grade				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2019 – Present	[redacted]	Hyderabad	Telangana	500033
01/2014 – 06/2019	[redacted]	Hyderabad	Telangana	500033
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD, TS INDIA
NOTARY
Regn No 198
F.102

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Novadoz Pharmaceuticals, LLC			08/2018 - Present
Business Address	**City**	**State**	**Zip**
20 Duke Road, Suite A	Piscataway	NJ	08854
Phone	**Title**		
(551) 777-0575	Shareholder/Director (86.51% Ownership)		
Description of Duties			
Leads critical functions such as Finance, Supply Chain & Operational excellence ensure that the company consistently delivers the highest quality services while maintaining affordability			

Business Name			From - To (MM/YY – MM/YY)
MSN Laboratories Pvt. Limited			2014 - 2018
Business Address	**City**	**State**	**Zip**
MSN Corporate, H.No. 2-91/10 311/MSN, Whitefields,	Kondapur, 500084		
Phone	**Title**		
040 - 3043 - 8600			
Description of Duties			
Overseeing and managing the finance & supply functions within the organization. Duties include handling financial planning, budgeting, & analysis, to ensure the company's financial Health. Additionally manages supply chain operations, ensuring the procurment, storage & distribution of goods & materials			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.



Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

M. SADA SIVA KUMAR REDDY ADVOCATE
NOTARY
Regn No 198
F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD, TS INDIA

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
F-102, KUKATPALLY, HYDERABAD, TS, INDIA
NOTARY
Regn No 198

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

M. SADA SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD, TS, INDIA
NOTARY
Regn No 198
F-102

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Manne Sindhuja Reddy

Print Name (First, Last)

M Sindhuja

Original Signature (electronic, copies or stamps not accepted)

2 May 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Telangana, ss. County of INDIA

I, Manne Sindhuja Reddy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

M Sindhuja

Original Signature Manne Sindhuja Reddy

2 May 2024

Date

Subscribed and Sworn to before me this 4th day of May '24.

Notary Public Signature

ATTESTED

M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony
Kukatpally, Hyderabad, TS India (Ph:98480 44395

M. SADA SIVA KUMAR REDDY ADVOCATE ★ SARASWATHI ENCLAVE ★ BHAGYANAGAR COLONY ★ KUKATPALLY HYDERABAD TS INDIA ★ F-102 NOTARY Regn. No. 198 NOTARIAL

(Seal)

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02146	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Societal CDMO Gainesville, LLC

Physical Address: 1300 Gould Drive

City: Gainesville State: GA Zip: 30504

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 770.534.8239 Website: www.societalCDMO.com

Name of Designated Representative (DR): David Smithwick

Licensing Company Email: Liz.Radke@SocietalCDMO.com DR Email: David.Smithwick@SocietalCDMO.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Legend Pharmaceuticals	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Recordati
Address: 100 Corporate Drive City: Lebanon State: NJ Zip: 08833

Name: Veranova Pharmaceutical Company
Address: 2003 Nolte Drive City: West Depford State: NJ Zip: 08086

Name: Lonza Greenwood LLC
Address: 105 Capsugel Court City: Greenwood State: SC Zip: 29646

Name: Cambrex Charles City Inc.
Address: 1205 11th Street City: Charles City State: IA Zip: 50616

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Massachusetts
Parent Company (if any): Societal CDMO, Inc.
Corporation/Organization Name: Societal CDMO Gainesville, LLC
Mailing Address: 1300 Gould Drive
City: Gainesville State: GA Zip: 30504
Telephone: 770-534-8239 Email: scott.rizzo@societalcdmo.com
Contact Person Name: M. Scott Rizzo

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Societal CDMO Gainesville, LLC

Facility Name

David Smithwick

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/29/24

Date

Board Use Only	Date Received: 11/4/24	Amount: $1000 CK 109769

An official website of the United States government Here's how you know

FDA

Drug Establishments Current Registration Site

New Search

Search Results for *Societal CDMO Gainesville, LLC*

Showing 1 to 1 of 1 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Societal CDMO Gainesville, LLC	1035761	057585150	ANALYSIS; LABEL; MANUFACTURE; PACK	1300 Gould Drive, Gainesville, Georgia (GA) 30504, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Nov 13, 2024

New Search

LIST OF ALL OFFICERS
CORERX, INC., SOCIETAL CDMO, INC. & SOCIETAL CDMO GAINESVILLE, LLC

CoreRx, Inc.
14205 Myerlake Circle
Clearwater, FL 33760
727-259-6950

Name	***Office***
Owen Murray	*Chief Executive Officer*
Scott Rizzo	*Chief Operating Officer*
Anders Forsell	*Chief Financial Officer and Treasurer*
Dan Dobry	*Chief Strategy Officer*
Gwen Green	*Chief Commercial Officer*
Leanne Ryan	*Secretary*

CoreRx, Inc owns 100% of Societal CDMO, Inc.
++

Societal CDMO, Inc.
1300 Gould Drive
Gainesville, GA 30504
770.531.8100

Name	***Office***
Owen Murray	*Chief Executive Officer and President*
Scott Rizzo	*Chief Operating Officer*
Anders Forsell	*Chief Financial Officer and Treasurer*
Dan Dobry	*Chief Strategy Officer*
Gwen Green	*Chief Commercial Officer*
Leanne Ryan	*Secretary*

Societal CDMO, Inc. owns 100% of Societal CDMO Gainesville, LLC
++

Societal CDMO Gainesville, LLC
1300 Gould Drive
Gainesville, GA 30504
706.531.8100

Name	***Office***
Owen Murray	*Chief Executive Officer and President*
Scott Rizzo	*Chief Operating Officer*
Anders Forsell	*Chief Financial Officer and Treasurer*
Dan Dobry	*Chief Strategy Officer*
Gwen Green	*Chief Commercial Officer*
Leanne Ryan	*Secretary*

SOCIETAL CDMO, INC.
Organizational Ownership Chart
(14July2024)

NQ PE Project Stingray Parent, L.P.

- Cayman entity
- Owner's name with 10% or greater ownership interest:
  - Allstate Insurance Company
  - Capital Dynamics Mid-Market Direct V (Lux) SCSp
  - NovaQuest Private Equity Fund I, L.P.

NQ PE Project Stingray Topco Inc.

- USA entity
- NQ PE Project Stingray Parent, L.P., owns 100% of NQ PE Project Stingray Topco Inc.

NQ PE Project Stingray Midco Inc.

- USA entity
- NQ PE Project Stingray Topco Inc. owns 100% of NQ PE Project Stingray Midco Inc.

CoreRx, Inc.

- USA entity
- NQ PE Project Stingray Midco Inc. owns 100% of CoreRx, Inc.

Societal CDMO, Inc.

- USA entity
- CoreRx, Inc., owns 100% of Societal CDMO, Inc.

Societal CDMO, Inc., owns 100% of its following subsidiaries (all are USA entities):

- Societal CDMO, Inc.
- Societal CDMO Gainesville, LLC
- Societal CDMO Gainesville Development, LLC
- Societal CDMO San Diego, LLC

Control Number : K318007

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

Societal CDMO Gainesville, LLC
a **Foreign Limited Liability Company**

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 28168496
Date Inc/Auth/Filed:	08/10/1993
Jurisdiction	: Massachusetts
Print Date	: 10/16/2024
Form Number	: 211

Brad Raffensperger

Brad Raffensperger
Secretary of State

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Societal CDMO Gainesville, LLC

Nevada Business Identification # NV20243215507
Expiration Date: 10/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 10/08/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202410085030282
You may verify this certificate online at https://www.nvsilverflume.gov/home

STATE OF GEORGIA
Georgia Board of Pharmacy
Manufacturing Pharmacy
LICENSE NO. PHMA000642 Status: Active

Societal CDMO Gainesville LLC
1300 Gould Drive
Gainesville GA 30504

Expires: 06/30/2025
Issued: 08/19/2024

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Manufacturing Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Manufacturing Pharmacy
LICENSE NO. PHMA000642 Status: Active
Societal CDMO Gainesville LLC
1300 Gould Drive
Gainesville GA 30504

Expires: 06/30/2025
Issued: 08/19/2024
Real-time license verification is available at gadch.mylicense.com/verification

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0483153	02-28-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,4,L1	MANUFACTURER	01-29-2024

SOCIETAL CDMO GAINESVILLE LLC
1300 GOULD DR
GAINESVILLE, GA 30504

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0483153	02-28-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,4,L1	MANUFACTURER	01-29-2024

SOCIETAL CDMO GAINESVILLE LLC
1300 GOULD DR
GAINESVILLE, GA 30504

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0483153	02-28-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,4,L1	MANUFACTURER	01-29-2024

SOCIETAL CDMO GAINESVILLE LLC
1300 GOULD DR
GAINESVILLE, GA 30504

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
1724 9143 9150 9193 9250 9300 9668 7435 7439 7370 7405 7437 7438 1100

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 810019855

Application/License No. WH02146

Societal CDMO Gainesville, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1300 Gould Drive Gainesville, GA 30504 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800 Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 11, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of October, 20 24.

APPLICANT/PRINCIPAL

Societal CDMO Gainesville, LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Oana Dimulescu, Attorney-in-fact
print name

SEAL

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ryan Norman

Witness Ashley Burns

Countersigned by:

N/A
Nevada Resident Agent

ELIZABETH CARTER
Notary Public - State of Florida
Commission # HH 394767
My Comm. Expires May 4, 2027
Bonded through National Notary Assn.

Posted February 20, 2020

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Bradley Mapes, Jodi L. Jennings, Oana R Dimulescu, Ryan Norman, Sarah C. Belcastro, Shana Kae Meyer, Stephen A. Vann,** each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 11th day of October, 2024

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to [redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Societal CDMO Gainesville, LLC

Pharmacy/Wholesaler License # (if applicable): WH02146

Physical Address: 1300 Gould Drive

City: Gainesville State: GA Zip: 30504

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 770.534.8239 Website: www.societalcdmo.com

Licensing Company Email: liz.radke@societalcdmo.com

Section 2: Personal Information

First: David Middle: Carroll Last: Smithwick

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 1300 Gould Drive

City: Gainesville State: GA Zip: 30504

Telephone: 770.534.8239 Email: david.smithwick@societalcdmo.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lawrence Academy		09/1978 - 06/1981	
Address	City	State	Zip
	Merry Hill	NC	27957
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
East Carolina University		08/1981 - 07/1986	
Address	City	State	Zip
	Greenville	NC	27834
Diploma/Degree obtained, if any			
BS Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2018 - Current	[redacted]	Cumming	GA	30041
03/1994 - 07-2017		Greenville	NC	28734
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Societal CDMO Gainesvillle LLC			08/2018 - Current	
Business Address		**City**	**State**	**Zip**
1300 Gould Drive		Gainesville	GA	30504
Phone	**Title**		**Number of Employed Hours**	
770-534-8239	Vice President Operations and Site Head		12,000	
Description of Duties				
Manage/responsible for the mfg/distribution of pharmaceutical operations on site employing approximately 160 employees.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

Date

I, David C. Smithwick, **certify that as the designated representative for**

Societal CDMO Gainesville LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Smithwick
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/31/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Smithwick

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/31/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Hall

I, Amy T. Hendrix, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

A. T. Hendrix

Original Signature

10-31-24

Date

Subscribed and Sworn to before me this 31ST day of October

A. T. Hendrix

Notary Public Signature

NOTARY PUBLIC, HALL COUNTY GEORGIA
MY COMMISSION EXPIRES AUG. 30, 2027

(Seal)

Adams, Jessica	Quality Assurance - GA	Georgia - Gould
Ahmed, Sarah M.	Facilities - GA	Georgia - Gould
Alban, Allen Jay I.	Analytical Dev - GA	Georgia - Gould
Allen Jr., Darren	Validation - GA	Georgia - Gould
Allen, Cheryl R.	Quality Assurance - GA	Georgia - Gould
Alvarado Rivera, Liz E.	Quality Assurance - GA	Georgia - Gould
Alvarado, Jacob	Facilities - GA	Georgia - Gould
Andal, Mutya	Facilities - GA	Georgia - Gould
Anderson, Alexander	Quality Control - GA	Georgia - Gould
Appling, Mark G.	Quality Control - GA	Georgia - Gould
Arrowood, Myra E.	Warehouse - GA	Georgia - Gould
Ballard, Clinton	Validation - GA	Georgia - Gould
Barrick, Josef E.	Facilities - GA	Georgia - Gould
Bass, Stanley	Facilities - GA	Georgia - Gould
Bass, Wendy	Information Technology	Georgia - Gould
Baugh, Dion K.	Manufacturing- GA	Georgia - Gould
Baugh, Linda D.	Materials Mgt-Purchasing	Georgia - Gould
Beckwith, Tiffany	Quality Control - GA	Georgia - Gould
Bonet-Vazquez, Carlos E.	EHS	Georgia - Gould
Bonilla, Claudia K.	Manufacturing- GA	Georgia - Gould
Boushelle, Keith A.	Manufacturing- GA	Georgia - Gould
Breazeale, Gary K.	Manufacturing- GA	Georgia - Gould
Campbell, Marc L.	Manufacturing- GA	Georgia - Gould
Carlson, Brandon L.	Quality Control - GA	Georgia - Gould
Carmona, Emily R.	Quality Assurance - GA	Georgia - Gould
Carson, Sharon	Quality Control - GA	Georgia - Gould
Carter, Sharon	Manufacturing- GA	Georgia - Gould
Castillo, Antonio	Facilities - GA	Georgia - Gould
Cervantes Vargas, Luis M.	Manufacturing- GA	Georgia - Gould
Chafin, Sierra V.	Quality Control - GA	Georgia - Gould
Champion, Daniel G.	Quality Assurance - GA	Georgia - Gould
Chatman, Martha M.	Warehouse - GA	Georgia - Gould
Chauhan, Ruchitaben	Analytical Dev - GA	Georgia - Gould
Christensen, Joseph A.	Quality Control - GA	Georgia - Gould
Christian, Julie	Facilities - GA	Georgia - Gould
Cochran, Justin	Warehouse - GA	Georgia - Gould

Corpin, Mary Ann G.	Manufacturing- GA	Georgia - Gould
Desai, Jigna U.	Quality Assurance - GA	Georgia - Gould
Diaz, Diego R.	Manufacturing- GA	Georgia - Gould
Do, Lynn N.	Quality Control - GA	Georgia - Gould
Dodaro, Juan	Information Technology	Georgia - Gould
Dumanowsky, Logan B.	Quality Control - GA	Georgia - Gould
Evans, Dana L.	Quality Assurance - GA	Georgia - Gould
Fabiny, Samuel	Quality Control - GA	Georgia - Gould
Facemire, John W.	Manufacturing- GA	Georgia - Gould
Feher, Rebecca	Quality Assurance - GA	Georgia - Gould
Ferraro, Jennifer C.	Validation - GA	Georgia - Gould
Friel, John D.	Manufacturing- GA	Georgia - Gould
Friel, Tina	Packaging - GA	Georgia - Gould
Fromm, Susan M.	Quality Assurance - GA	Georgia - Gould
Gannaram, Srikanth	Quality Control - GA	Georgia - Gould
Gass, Jonathan K.	Quality Control - GA	Georgia - Gould
Ge, Jingxuan	Analytical Dev - GA	Georgia - Gould
Giles, Brittany N.	Quality Assurance - GA	Georgia - Gould
Gillam, Mallory E.	Analytical Dev - GA	Georgia - Gould
Goss, Jeffery B.	Packaging - GA	Georgia - Gould
Grainger, Anthony C.	Packaging - GA	Georgia - Gould
Green, Walter	Quality Control - GA	Georgia - Gould
Griffin, Martha S.	Clinical Trial Services	Georgia - Gould
Griffin, Stephanie	Quality Assurance - GA	Georgia - Gould
Hampton, Ian W.	Facilities - GA	Georgia - Gould
Harkins, Korey E.	Warehouse - GA	Georgia - Gould
Harris, Kaya J.	Manufacturing- GA	Georgia - Gould
Harris, Sabrina R.	Manufacturing- GA	Georgia - Gould
Hart, Kelsey	Quality Control - GA	Georgia - Gould
Hawkins, Karena V.	Quality Control - GA	Georgia - Gould
Hendrix, Amy T.	Human Resources	Georgia - Gould
Holland, Gregory R.	Materials Mgt-Purchasing	Georgia - Gould
House, Lea P.	Quality Assurance - GA	Georgia - Gould
Huynh, Luan	Quality Control - GA	Georgia - Gould
Jamil, Shazib	Materials Mgt-Purchasing	Georgia - Gould
Jenkins, Jeffrey M.	Facilities - GA	Georgia - Gould
Johnson, Jamie L.	Information Technology	Georgia - Gould

Jordan, Robert O.	Warehouse - GA	Georgia - Gould
Jozefiak, Karen	Regulatory Affairs	Georgia - Gould
Kidd, James M.	Quality Control - GA	Georgia - Gould
Killi, Gnana Deepika	Analytical Dev - GA	Georgia - Gould
Kim, Justin H.	Analytical Dev - GA	Georgia - Gould
King, Chantin	Manufacturing- GA	Georgia - Gould
Kolikoviski, Lucas	Facilities - GA	Georgia - Gould
Kose, Jody	Warehouse - GA	Georgia - Gould
Lam, Nam	Manufacturing- GA	Georgia - Gould
Lee, Benjamin	Packaging - GA	Georgia - Gould
Lezama, Nikki	Human Resources	Georgia - Gould
Lowder, Richard D.	Facilities - GA	Georgia - Gould
Lukers, Malinda S.	Finance	Georgia - Gould
Mallamgari, Sheshank Reddy	Analytical Dev - GA	Georgia - Gould
Mangum, Philip C.	Materials Mgt-Purchasing	Georgia - Gould
Mangum, Tiphiny M.	Packaging - GA	Georgia - Gould
Marshall Jr., Leroy A.	Manufacturing- GA	Georgia - Gould
Martin, Sarah G.	Quality Control - GA	Georgia - Gould
Martinez, Benjamin T.	Quality Control - GA	Georgia - Gould
Martinez, Jennifer	Warehouse - GA	Georgia - Gould
Maskarenas, Charmaine I.	Human Resources	Georgia - Gould
Mathis, Sandra L.	Human Resources	Georgia - Gould
McCurry, Christopher T.	Manufacturing- GA	Georgia - Gould
McDougal, Bernard B.	Manufacturing- GA	Georgia - Gould
McDowell, Sharon L.	Regulatory Affairs	Georgia - Gould
Mendoza-Guerra, Aldo E.	Manufacturing- GA	Georgia - Gould
Meng, Yunjing	Analytical Dev - GA	Georgia - Gould
Meza, Juan	Warehouse - GA	Georgia - Gould
Michael, Hubert W.	Manufacturing- GA	Georgia - Gould
Millwood, Jeremy B.	Quality Assurance - GA	Georgia - Gould
Mistry, Nehal U.	Analytical Dev - GA	Georgia - Gould
Modi, Umangi P.	Analytical Dev - GA	Georgia - Gould
Montero, Carolina	Manufacturing- GA	Georgia - Gould
Morgan Jr., Frederick D.	Manufacturing- GA	Georgia - Gould
Morse, Sandra	Materials Mgt-Purchasing	Georgia - Gould
Murphy, Alicia	Quality Control - GA	Georgia - Gould
Myers, Karen E.	Quality Assurance - GA	Georgia - Gould

Najarian, Daphne	Quality Assurance - GA	Georgia - Gould
Nguyen, Thao T.	Quality Control - GA	Georgia - Gould
Nicholson, Gregg	Quality Control - GA	Georgia - Gould
Njau, John N.	Manufacturing- GA	Georgia - Gould
Norman, Taylor A.	Quality Control - GA	Georgia - Gould
Nunez Castillo, Jorge	Manufacturing- GA	Georgia - Gould
ODonnell, Devin S.	Manufacturing- GA	Georgia - Gould
Patel, Devyani D.	Analytical Dev - GA	Georgia - Gould
Patel, Harnish	Quality Control - GA	Georgia - Gould
Pedada, Kiran K.	Analytical Dev - GA	Georgia - Gould
Peters, Hollie S.	Analytical Dev - GA	Georgia - Gould
Phimmachack, Kris S.	Manufacturing- GA	Georgia - Gould
Quiroz, Luis	Manufacturing- GA	Georgia - Gould
Radke, Elizabeth C.	Regulatory Affairs	Georgia - Gould
Randall, Jonathan	Finance	Georgia - Gould
Reza, Md Asmaul	Analytical Dev - GA	Georgia - Gould
Rincon Reyes, Melissa	Quality Control - GA	Georgia - Gould
Rivera, Giana I.	Quality Control - GA	Georgia - Gould
Roach, Timothy D.	Facilities - GA	Georgia - Gould
Rucker, Dwight N.	Facilities - GA	Georgia - Gould
Sailers, Harry T.	Warehouse - GA	Georgia - Gould
Sams, Bradley R.	Facilities - GA	Georgia - Gould
Santos, Edwin A.	Facilities - GA	Georgia - Gould
Sapp, Christopher J.	Manufacturing- GA	Georgia - Gould
Sargent, Alan T.	Warehouse - GA	Georgia - Gould
Seibt, Joseph D.	Analytical Dev - GA	Georgia - Gould
Shapiro, Anne Marie	Facilities - GA	Georgia - Gould
Sharma, Swati	Analytical Dev - GA	Georgia - Gould
Simmons, Stephon	Manufacturing- GA	Georgia - Gould
Smith, Gerald F.	Packaging - GA	Georgia - Gould
Smith, Stephanie M.	Quality Assurance - GA	Georgia - Gould
Smith, Timothy	Manufacturing- GA	Georgia - Gould
Smithwick, David C.	Operations Mgmt - GA	Georgia - Gould
Stephens, Jacquez R.	Manufacturing- GA	Georgia - Gould
Stone, Rebekah G.	Analytical Dev - GA	Georgia - Gould
Strickland, Betty J.	Warehouse - GA	Georgia - Gould
Swegman, Chelsea L.	Quality Control - GA	Georgia - Gould

Swinney, Tonyor B.	Quality Assurance - GA	Georgia - Gould
Ta, My-Van	Materials Mgt-Purchasing	Georgia - Gould
Thota, Manjula V.	Analytical Dev - GA	Georgia - Gould
Tillirson, Wendy	EHS	Georgia - Gould
Valiente Chacin, Gerardo J.	Facilities - GA	Georgia - Gould
Vandiver, Sherida R.	Quality Assurance - GA	Georgia - Gould
Vaughn, Carolyn L.	Facilities - GA	Georgia - Gould
Vaughn, Kipling D.	Facilities - GA	Georgia - Gould
Velazquez, Orlando	Validation - GA	Georgia - Gould
Vest, Yennifer	Manufacturing- GA	Georgia - Gould
Vo, Aithi	Quality Assurance - GA	Georgia - Gould
Vohra, Rafiq A.	Facilities - GA	Georgia - Gould
Walden, Ema C.	Warehouse - GA	Georgia - Gould
Wallace, Ciara H.	Quality Control - GA	Georgia - Gould
Wallace, James	Manufacturing- GA	Georgia - Gould
Wiant, Susan M.	Quality Control - GA	Georgia - Gould
Wiley, Roger W.	Regulatory Affairs	Georgia - Gould
Williams, Natalie N.	Manufacturing- GA	Georgia - Gould
Wood, Janice	Quality Assurance - GA	Georgia - Gould
Yacobacci, Anthony B.	Information Technology	Georgia - Gould
Young, Cara	Business Development	Georgia - Gould
Colon Diaz, Marta M.	Project Management	Georgia Remote
Dress, Stephen P.	Information Technology	Georgia Remote
Green, Gwen	Business Development	Georgia Remote
Kramel, Nadine	Project Management	Georgia Remote
Murray, Owen	SGA Executive	Georgia Remote
Ocampo, Michael B.	Project Management	Georgia Remote
Porter, Robyn	Human Resources	Georgia Remote
Randall, River E.	Finance	Georgia Remote
Rizzo, Marshall S.	Operations Mgmt - GA	Georgia Remote
Savage, Dana L.	Project Management	Georgia Remote
Showfety, Mary G.	SGA Executive	Georgia Remote
Sidwell, Richard A.	Innovation-Proposal Mgmt	Georgia Remote

- ***List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant***

Oaktree Fund Administration, LLC

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03576	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Valinor Pharma, LLC

Physical Address: 90 Washington Valley Rd, Ste 10

City: Bedminster State: NJ Zip: 07921

Mailing Address (if different from physical address): 360 Mt Kemble Ave 3rd Floor

City: Morristown State: NJ Zip: 07960

Telephone: (833)233-0115 Website: https://valinorrx.com/

Name of Designated Representative (DR): Michelle Collura

Licensing Company Email: info@valinorrx.com DR Email: michelle.collura@averitaspharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Physician offices, Retail		☒ Others: Virtual Manufacturers

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No supplies sold, dispensed or distributed within past year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Movanitk Acquisition Co.

Corporation/Organization Name: Valinor Pharma, LLC

Mailing Address: 90 Washington Valley Rd, Ste 10

City: Bedminster State: NJ Zip: 07921

Telephone: (833)233-0115 Email: megan.renze@grunenthal.com

Contact Person Name: Megan Renze, Manager

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: **Valinor Pharma, LLC has a labeler code. Please see attached.**		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Valinor Pharma, LLC

Facility Name

Megan Renze, Manager

Print Name of Authorized Person Submitting Application

Megan Renze

Original signature of Authorized Person (copies or stamps not accepted)

7/24/2024

Date

Board Use Only	Date Received: 8/19/24	Amount: $1000-CK 8805254

Valinor Pharma, LLC
FEIN #: 86-2292762

FDA Labeler Code Information and Bond Rider in the Amount of $25,000

From: [redacted]
To: [redacted]
Subject: FW: Labeler Code Request Approved - Valinor
Date: Friday, July 21, 2023 12:04:37 PM

Yang Chen
908-670-1351

From: Amy Wojtowicz <AWojtowicz@Valinorrx.com>
Sent: Wednesday, March 16, 2022 5:25 PM
To: Ben Bove <BBove@novosgrowth.com>
Cc: Yang Chen <YChen@novosgrowth.com>
Subject: FW: Labeler Code Request Approved - Valinor

Ben, Yang –

Good news -Valinor has been assigned a Labeler Code!

Let me know if you have any questions.

Thanks,
Amy

From: [redacted] <[redacted]>
Sent: Wednesday, March 16, 2022 10:19 AM
To: Amy Wojtowicz <[redacted]>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 16-MAR-2022
Labeler DUNS: 118035461
Labeler Name: Valinor Pharma, LLC
Labeler Code Assigned: 82625

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to

all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

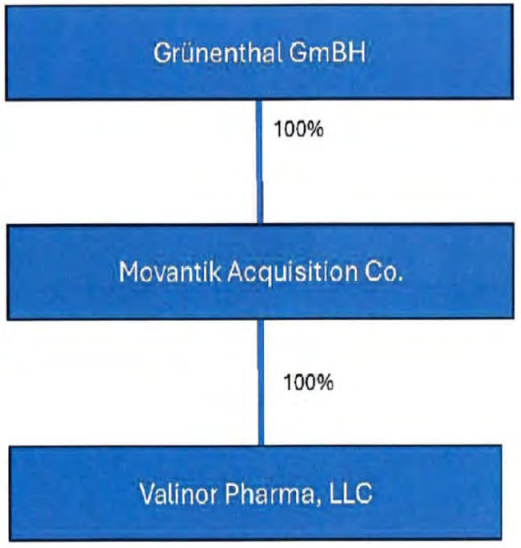
Valinor Pharma LLC
FEIN # 86-2292762

Directors and Officers for Valinor Pharma, LLC

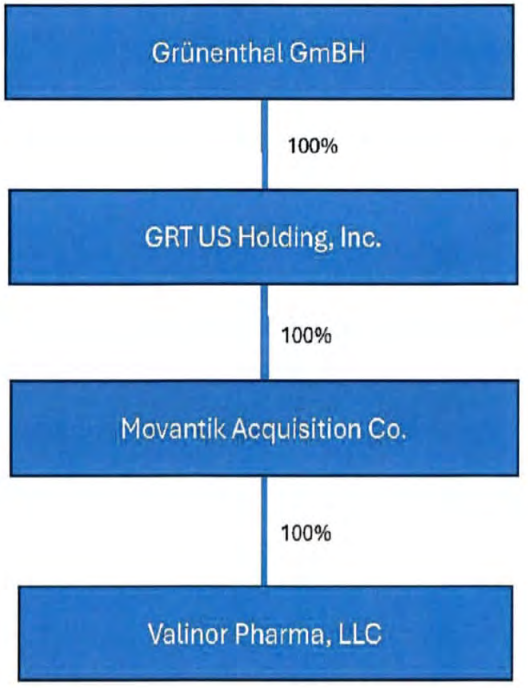
Name	Title
Megan Renze	Manager & President
Sunia Ho	Treasurer

Valinor Pharma, LLC

Current Organizational Structure



New Organizational Structure



STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

3 ***VALINOR PHARMA, LLC***
0450901301

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign Limited Liability Company was registered by this office on December 21, 2022.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 9th day of July, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6155085558

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VALINOR PHARMA, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5197918 8300

SR# 20243316013

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204082060

Date: 08-05-24

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0750649

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

90 WASHINGTON VALLEY RD. STE 10 BEDMINSTER, NJ 07921-

Reg. No.
5006220

VALINOR PHARMA, LLC
90 WASHINGTON VALLEY RD, STE 10
BEDMINSTER, NJ 07921-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

RIDER

To be attached to and form a part of Bond No. **810014907**

Effective:	**April 10, 2023**	
Bond Amount:	**$25,000.00**	
Executed by:	**Valinor Pharma, LLC**	as Principal
and by:	**Atlantic Specialty Insurance Company**	as Surety
in favor of:	**State of Nevada**	as Obligee

In consideration of the mutual agreements herein contained, the Principal and the Surety hereby consent to **amend the principal's address to**:

90 Washington Valley Road, Suite 10, Bedminster, NJ 07921

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective: **April 10, 2023**

Signed and Sealed: **October 9, 2023**

Principal: **Valinor Pharma, LLC**

By: _____
Principal

Surety: **Atlantic Specialty Insurance Company**

By: _____
James Moore, Attorney-in-Fact

STATE OF ILLINOIS

COUNTY OF DUPAGE)

On October 9, 2023, before me, Carrie Albertson, a Notary Public in and for said County and State, residing therein, duly commissioned and sworn, personally appeared, James Moore known to me to be Attorney-in-Fact of Atlantic Specialty Insurance Company the corporation described in and that executed the within and foregoing instrument, and known to me to be the person who executed the said instrument in behalf of the said corporation, and duly acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, the day and year stated in this certificate above.

My Commission Expires, May 10, 2027

Carrie Albertson, Notary Public

Commission No.971436

CARRIE ALBERTSON
OFFICIAL SEAL
Notary Public - State Of Illinois
My Commission Expires
05/10/2027

intact INSURANCE

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Kelly A. Gardner, Jennifer J. Mc Comb, James Moore, Stephen Kazmer, Dawn L. Morgan, Melissa A. Schmidt, Amy Wickett,** each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 9th day of October, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

Please direct bond verifications to [redacted]

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: BLUESTONE BROKERAGE LLC
Agency Code: 16-163278

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Courtney Gomez
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 16BSBJG0484
Naming Hashem Echad Corp dba Ecopharm as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of July 29, 2024.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

Valinor Pharma, LLC
FEIN #: 86-2292762

Medical Devices, Equipment and Gases (MDEG) Administrator Form and Proof of Insurance are Not Applicable.

Please note that Valinor Pharma, LLC does not wholesale medical devices, equipment, supplies, or gases.

Valinor Pharma, LLC
FEIN #: 86-2292762

Personal History Record Application is Not Applicable.

Please note that the sole member of Valinor Pharma, LLC is Movantik Acquisition Co.

Valinor Pharma, LLC
FEIN #: 86-2292762

Copy of DEA Registration is Not Required.

Please note that Valinor Pharma, LLC does not handle controlled substances.

Valinor Pharma, LLC
FEIN #: 86-2292762

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Valinor Pharma, LLC

Pharmacy/Wholesaler License # (if applicable) WH03576

Physical Address 90 Washington Valley Rd, Ste 10

City Bedminster State NJ Zip 07921

Mailing Address (if different from physical address) 360 Mt Kemble Ave 3rd Floor

City Morristown State NJ Zip 07960

Telephone (833)233-0115 Website https://valinorrx.com/

Licensing Company Email

Section 2: Personal Information

First Michelle Middle Johanna Last Collura

Alias(es, nicknames, name changes, etc.) Bird, Schlachet

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Columbus State OH Zip 43220

Telephone [redacted] Email michelle.collura@averitaspharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/98-08/04	
Address	**City**	**State**	**Zip**
201 Presidents' Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
Duchesne High School		08/94-05/98	
Address	**City**	**State**	**Zip**
155 E Main Street	Duchesne	UT	84021
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/24-Current	[redacted]	Far Hills	NJ	07931
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Averitas Pharmaceutical			06/23 - current	
Business Address	**City**		**State**	**Zip**
360 Mount Kemble Avenue	Morristown		NJ	07960
Phone	**Title**		**Number of Employed Hours**	
908-393-0047	Director, Trade Operations		2440	
Description of Duties				
I lead our trade and distribution channel, meaning I ensure our product is properly distributed to our end user customers. I work closely with our distribution partners to maintain proper inventory levels, record keeping, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Aurinia Pharmaceuticals			05/22 - 06/23	
Business Address	**City**		**State**	**Zip**
77 Upper Rock Cir Ste 700	Rockville		MD	20850
Phone	**Title**		**Number of Employed Hours**	
250-744-2487	Director, Distribution and Trade Operations		2320	
Description of Duties				
I lead our trade and distribution channel, meaning I ensure our product is properly distributed to our end user customers. I work closely with our distribution partners to maintain proper inventory levels, record keeping, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			12/19 - 04/22	
Business Address	**City**		**State**	**Zip**
7000 Cardinal Place	Dublin		OH	43017
Phone	**Title**		**Number of Employed Hours**	
614-757-5253	Director, Specialty Sourcing		5408	
Description of Duties				
I oversaw the distribution for over 300 manufacturers in the Cardinal SPD channel, which meant ensuring all the products were distributed properly, and to the correct locations and to the correct classes or trade, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Michelle Collura, **certify that as the designated representative for**

Averitas Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MJC I am at least 21 years of age;
3. MJC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MJC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MJC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MJC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MJC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michelle Collura

Print Name (First, Last)

MJC

Original Signature (electronic, copies or stamps not accepted)

8/15/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michelle Collura

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/15/24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Michelle Collura, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/15/24

Date

Subscribed and Sworn to before me this 15th day of August 2024 by Michelle Collura.

Roberta A. Neal

Notary Public Signature

ROBERTA A NEAL
Notary Public
State of Ohio
My Comm. Expires
January 26, 2025

(Seal)

Valinor Pharma, LLC
FEIN #: 86-2292762

List of Employee, Agent, Independent Contractor, or Consultant

Name	Title
Luis de Freitas Kietzmann	Manager
Megan Renze	Manager
Michelle Collura	Designated Representative

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02522	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Braeburn Inc.

Physical Address: 450 Plymouth Road, Suite 400

City: Plymouth Meeting State: PA Zip: 19462

Mailing Address (if different from physical address): 450 Plymouth Road, Suite 400

City: Plymouth Meeting State: PA Zip: 19462

Telephone: 610-467-8680 Website: https://braeburnrx.com/

Name of Designated Representative (DR): Michael Derkacz

Licensing Company Email: StateLicensing@braeburnrx.com DR Email: StateLicensing@braeburnrx.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Specialty pharmacies and specialty distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pharmaceutics International, Inc.
Address: 10819 Gilroy Road City: Hunt Valley State: MD Zip: 21031

Name: Sharp Packaging Services, LLC
Address: 7451 Keebler Way City: Allentown State: PA Zip: 18106

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): ATP Life Science Ventures, L.P.
Corporation/Organization Name: Braeburn Inc.
Mailing Address: 450 Plymouth Road, Suite 400
City: Plymouth Meeting State: PA Zip: 19462
Telephone: 610-467-8680 Email: StateLicensing@braeburnrx.com
Contact Person Name: Michael Derkacz

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	X	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Braeburn Inc.

Facility Name

Michael Derkacz

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/20/2024

Date

Board Use Only	Date Received: 11/26/24	Amount: $1000 CK 2054

NABP ACCREDITED
DRUG DISTRIBUTOR

Braeburn, Inc

located at

450 Plymouth Rd, Ste 400, Plymouth Meeting, PA 19462

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

05/13/2024 to 05/12/2027

Period of Accreditation

0924

An official website of the United States government Here's how you know

FDA U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov Menu

Home Drug Databases NDC Search Result

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Current through October 3, 2024

You have searched Finished drug products

Search Results: *'braeburn'*

Back to Search Page

Keyword Search RESET

Showing 1 to 7 of 7 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	P T
BRIXADI	58284-208-01	8mg/.16mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-208	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-216-01	16mg/.32mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-216	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-224-01	24mg/.48mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-224	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-228-01	128mg/.36mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-228	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-232-01	32mg/.64mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-232	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-264-01	64mg/.18mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-264	BUPRENORPHINE	BUPRENORPHINE	H F D
BRIXADI	58284-296-01	96mg/.27mL	INJECTION	SUBCUTANEOUS	NDA210136	Braeburn Inc.	58284-296	BUPRENORPHINE	BUPRENORPHINE	H F D

Previous 1 Next

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration

Attachment D

Corporation Information

Corporate Officers

Michael Derkacz
President and CEO

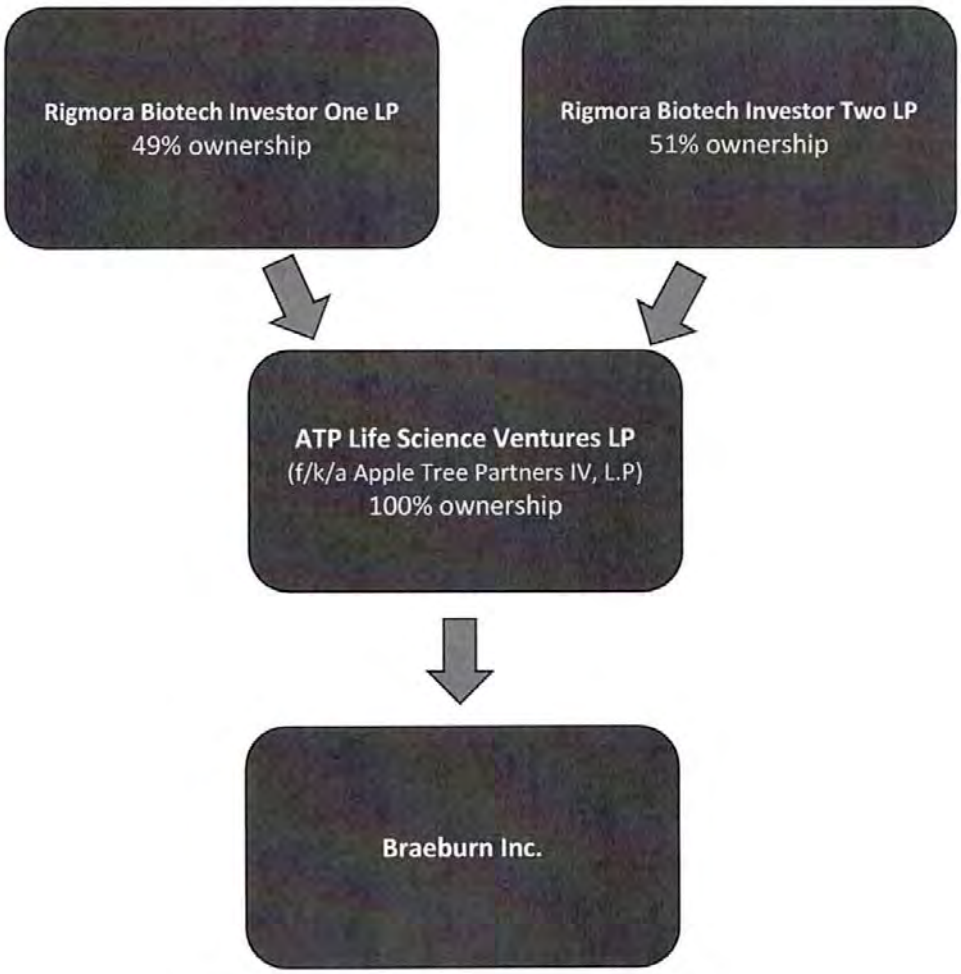
Louis Ricigliano
Chief Financial Officer & Assistant Secretary

Brian Hirsch
General Counsel and Secretary

Parent Company

ATP Life Science Ventures, L.P.
230 Park Avenue, Suite 2800, New York, NY 10169
Percent ownership: 100

Ownership Organization Chart



Delaware

The First State

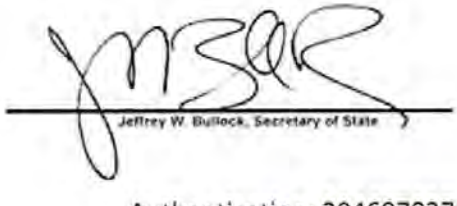
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BRAEBURN INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BRAEBURN INC." WAS INCORPORATED ON THE TWENTY-FIRST DAY OF SEPTEMBER, A.D. 2012.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





5216418 8300

SR# 20243922793

Authentication: 204607027

Date: 10-10-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Record

Certificate No. 9500000182

Drug & Device Registration

2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Office/Corporate Location
No product onsite

BRAEBURN INC.
450 PLYMOUTH RD
SUITE 400
PLYMOUTH MEETING, PA 19462

The above business is recognized by the Department of Health as an entity that is doing business in the Commonwealth of Pennsylvania related to pharmaceuticals, medical devices, or cosmetics for which said entity **does not** physically handle, possess, transfer, manufacture, distribute, or retail pharmaceuticals, medical devices or cosmetics at the location on the certificate of record.

Issuance Date: August 13, 2018

Expiration Date: The Last Day of August, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

pennsylvania
DEPARTMENT OF HEALTH

August 5, 2024

717.787.4779

Braeburn Inc.
450 Plymouth Rd
Suite 400
Plymouth Meeting, PA 19462

Dear Sir or Madam:

The Pennsylvania Department of Health, Drug, Device & Cosmetic Program acknowledges that the company, Braeburn Inc., is an entity within the Commonwealth that is performing business activities related to the pharmaceutical, medical device, or cosmetic industry at the stated address. The company is not engaging in the physical manufacture, storage, distribution or retailing of product at this address.

The company has voluntarily provided information and has attested that no pharmaceutical product, medical device or cosmetic of any kind is physically manufactured, stored, distributed or retailed at the address stated above. This information serves only to place the company at the specified location, on file as a courtesy and does not subject it to any on-site inspection or regulatory requirements under the purview of this office. The information is recorded under record number #9500000182 and reviewed annually.

If at any time the business function changes and pharmaceutical product, medical devices or cosmetics are physically manufactured, stored, distributed or retailed at the address stated above, an application for registration/licensure will be required by Department of Health and the facility would be subject to all laws and regulations applicable to those activities. You may visit our website at https://apps.health.pa.gov/ddc/ or contact our office for additional information.

Sincerely,

Theresa A. Ritchie R.Ph.

Theresa A. Ritchie, R.Ph.
Drug & Device Program Specialist
Division of Home Health

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0248686	11-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	10-03-2024

INTEGRATED COMMERCIALIZATION SOLUTIONS, LLC
420 INTERNATIONAL BLVD
STE 500
BROOKS, KY 40109

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0248686	11-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	10-03-2024

INTEGRATED COMMERCIALIZATION SOLUTIONS, LLC
420 INTERNATIONAL BLVD
STE 500
BROOKS, KY 40109

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0248686	11-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	10-03-2024

INTEGRATED COMMERCIALIZATION SOLUTIONS, LLC
420 INTERNATIONAL BLVD
STE 500
BROOKS, KY 40109

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2010

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K40176597

Application/License No. _____

BRAEBURN, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
450 Plymouth Road, Suite 400 Plymouth Meeting, PA 19462, as
Address of Applicant/Principal
PRINCIPAL, and FEDERAL INSURANCE COMPANY, a
Surety Company
corporation organized under the laws of the state of IN
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
202B Hall's Mill Road Whitehouse Station, NJ 08889 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/31/2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of October, 2020.

APPLICANT/PRINCIPAL
BRAEBURN, INC.

Louis Ricagliano
Authorized Representative

SURETY COMPANY
FEDERAL INSURANCE COMPANY

Surety Company's Representative

Wayne G. McVaugh, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sara Owens

Witness Kaitlyn Malkowski

Countersigned by:

Nevada Resident Agent Wayne G. McVaugh, NV License No. 500206

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company

Know All by These Presents, That **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, and **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, do each hereby constitute and appoint Kimberly G. Sherrod of Columbus, Ohio; George Gionis, Vicki Johnston, Kaitlyn Malkowski, Elizabeth Marrero, Jaquanda Martin, Wayne G. McVaugh, Sara Owens, Patricia A. Rambo, Lori S. Shelton and Joanne C. Wagner of Philadelphia, Pennsylvania; Cathy H. Ho, Justin Johnson and Barbara L. Rutter of Pittsburgh, Pennsylvania----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY**, and **PACIFIC INDEMNITY COMPANY** have each executed and attested these presents and affixed their corporate seals on this **11th** day of **April, 2019.**

Dawn M. Chloros, Assistant Secretary

Stephen M Haney, Vice President

STATE OF NEW JERSEY

County of Hunterdon ss

On this **11th** day of **April, 2019,** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros, to me known to be Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros, being by me duly sworn, did depose and say that she is Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY and knows the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that she signed said Power of Attorney as Assistant Secretary of said Companies by like authority; and that she is acquainted with Stephen M. Haney, and knows him to be Vice President of said Companies; and that the signature of Stephen M. Haney, subscribed to said Power of Attorney is in the genuine handwriting of Stephen M. Haney, and was thereto subscribed by authority of said Companies and in deponent's presence.

Notarial Seal

ROSE CURTIS
NOTARY PUBLIC OF NEW JERSEY
No. 50072400
Commission Expires November 22, 2022

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect.
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this 20th day of October, 2020

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

DocuSign Envelope ID: CCF7D358-9B25-47C6-8B4C-6EAB7BF6431E

FEDERAL INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2019

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash and Short Term Investments	$ (429,780)	Outstanding Losses and Loss Expenses	$ 6,823,691
United States Government, State and Municipal Bonds	4,559,706	Reinsurance Payable on Losses and Expenses	1,433,250
Other Bonds	5,314,219	Unearned Premiums	2,014,727
Stocks	32,735	Ceded Reinsurance Premiums Payable	353,115
Other Invested Assets	1,029,733	Other Liabilities	849,544
TOTAL INVESTMENTS	10,506,613	TOTAL LIABILITIES	11,474,327
Investments in Affiliates:			
Great Northern Ins. Co.	395,442	Capital Stock	20,980
Vigilant Ins. Co.	341,290	Paid-In Surplus	2,711,474
Chubb Indemnity Ins. Co.	178,808	Unassigned Funds	1,306,881
Chubb National Ins. Co.	181,053		
Other Affiliates	97,150	SURPLUS TO POLICYHOLDERS	4,039,335
Premiums Receivable	1,511,096		
Other Assets	2,302,210		
TOTAL ADMITTED ASSETS	$ 15,513,662	TOTAL LIABILITIES AND SURPLUS	$ 15,513,662

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners, At December 31, 2019, investments with a carrying value of $508,749,121 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Federal Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2019.

Sworn before me this April 14, 2020

DocuSigned by:
John Taylor
D28C1F6D5...

Senior Vice President

Diane Wright
Notary Public

August 8, 2023
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2023
Commission number 1235745
Member, Pennsylvania Association of Notaries

Attachment F

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Braeburn Inc.

Pharmacy/Wholesaler License # (if applicable) WH02522

Physical Address 450 Plymouth Road, Suite 400

City Plymouth Meeting State PA Zip 19462

Mailing Address (if different from physical address) 450 Plymouth Road, Suite 400

City Plymouth Meeting State PA Zip 19462

Telephone 610-467-8680 Website https://braeburnrx.com/

Licensing Company Email StateLicensing@braeburnrx.com

Section 2: Personal Information

First Michael Middle Moore Last Derkacz

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Berwyn State PA Zip 19312

Telephone 610-467-8680 Email StateLicensing@braeburnrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Texas at Arlington		09/82 - 05/91	
Address	**City**	**State**	**Zip**
701 Nedderman Dr.	Arlington	TX	76019
Diploma/Degree obtained, if any			
BA Communications/Advertising; Minor Business Administration/Marketing			

School Name		From - To (MM/YY – MM/YY)	
South Grand Prairie High School		09/82 - 05/91	
Address	**City**	**State**	**Zip**
301 Warrior Trail	Grand Prairie	TX	76019
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/09 - Present	[redacted]	Berwyn	PA	19312
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Braeburn Inc.		06/17 - Present	
Business Address	**City**	**State**	**Zip**
450 Plymouth Road, Suite 400	Plymouth Meeting	PA	19462
Phone	**Title**	**Number of Employed Hours**	
610-467-8680	President and CEO	40 wk	

Description of Duties

Serve on Board of Directors, management committees, and other governing boards. Works closely with the CFO to prepare annual budgets, complete risk analysis on potential investments, and advise Board regarding investment risk and return. Partner with the CCO in developing all aspects of commercial and business strategy, including market access, pricing, and reimbursement. Oversee all operations and business activities to ensure they produce desired results and are consistent with the overall strategy and mission. Enforce adherence to regulatory and legal guidelines and in-house compliance policies to maintain the company's adherence to applicable laws and regulations. Review financial and non-financial reports to devise solutions and improvements.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Michael Derkacz, **certify that as the designated representative for**

Braeburn Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Derkacz

Print Name (First, Last)

Original Signature (~~electronic, copies or stamps not accepted~~)

11/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Derkacz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of PENNSYLVANIA, ss. County of MONTGOMERY

I, MICHAEL DERKACZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/2024

Date

Subscribed and Sworn to before me this 20 day of NOVEMBER 2024 BY MICHAEL DERKACZ.

Notary Public Signature LINDSEY MCGONIGAL

(Seal)

Commonwealth of Pennsylvania - Notary Seal
Lindsey McGonigal, Notary Public
Montgomery County
My commission expires February 3, 2026
Commission number 1413536
Member, Pennsylvania Association of Notaries

Grothe,Deron
Padilla,Raymond
Kuper,Jennifer Ann
Fecko,Stephanie Ann
Plotner,Michelle
Merritt,Amy Lynn
Chiari,Katherine Eileen
Bloor,Daniel
Bianchi-Martinez,Sandra
Connolly JR,Thomas
Harris,Kendell
Levy,Seth Wayne
Schroeder,Kevin Thomas
Taylor,Ashley
Katrichis,Kelly
Boyer,Nicholas
Dowd,Natasha
Beal JR,Lawrence Kelly
Hirsch,Brian
Ehrlich,David
Aguilar,Mark
Casale,Rebecca
Sheehan,Kristen S
Deshotel,Susanna
Rond,Christopher
Robbie,David
Willimann,Whitney McMillian
Huber,Joelle Kay
Derkacz,Michael
Lorenz,Kevin
Hough,Julia Diane
Manendo,Eric
Williams,Alisa
Johnson,Jennifer Lynn
Granger,Donald
Nolan,Rhonda
McNicholas,Carri
Murtha,Nicholas C
Justus,Christina
Beal,Ryan
Aguanno,Alyson
O'Hara,Lauren
Carter,Celeta Fatima
Squires,James

CONFIDENTAIL

Matejek,Amy
Brosseau,Terra
Potter,Lisbeth
Pfohl,Nichole
Powell,Justin
Ballinger,Shannon White
Abraham,Christine
Walton,Peter Shaun
Melfi,Richard
Hyles,Kirt
Schimpf-Peterson,Megan
Sagle,Nathanial
Sayre,Allison
Randolph,Keisha
Simerton,Charmaine
Coltharp,Jennifer Hobbs
Wolff,Meryl
Loutzenhiser,Timothy
Smith Sniezak,Stacy
Copp,Susan Elizabeth
Cacioppo,Mario
Saltmer,Colleen
Wyman,Shawn
Bennett,Laurie
Belim,Chanel
Williamson,Angela Faith
Guagenti,Jacqueline
Deck,Nathan Jon
Field,William
Eash,Christopher
Norden,Joseph
Sanders,Shannon
Garrison-DeCost,Lisa Marie
Rondeau,Melissa
Meadows,Patrick John
Datres,Richard Allen
Debnam-White,Lashanda
Fellows,James Tyler
Duckworth,Brian
Bromley,Jordan
Maloy,Richard
Caruso,Louis
Pulis,AnnMarie
Rogers,Kala

CONFIDENTAIL

Novello,Kelly
Martin,Kyla Phelps
Laverty,Robert J
Cohen,Joshua
Lawrence,David
Golmon,Gwenda Lynn
Wrafter,Dena
Hilton,Sunshine
Schmidt,Lori
Williams,Christian
Mackey,Jeffrey
Kuleba,Barbara Ann
Gonzalez,Lisa
Curtis,Jill
Kannambille,Ruchira
Kim,Stephen
Seitz,Aari
Banton,Enid
Wood,Mark
Araujo,Margaret
Lovvoll,Vikki
Johnson,Paul
Taylor,Meredith
Trumbore,Lauren
DeSocio,Michael
Urick,Rae Ann
Shah,Grishma
Rauth,Renata
DeMicco,James Tyler
Williams,Daniel
Angstadt,Mason
Castro-Escobar,Natalia
Landis,John
Curtin,William
Popoli,Alan
Pfieffer,Shannon
Stewart,James
Crespo,Michelle
Shanfelt,Nancy Marshall
Faylor,Joshua
Hoffman,Laura
Miller,Wendy
Elms,Shawn
Ahmadi,Simren

CONFIDENTAIL

Gribbin,Nicole
Harris,Evan
Ruhno,Edward John
Budilovsky-Kelley,Natalie
Smith,Zachary Tyler
Maron,Allyson
Maxwell,Kendra
Frye,Neely
Thomas,Tracie
Romano,Sabrina
Tran,Tran
Melbourne,Jennifer Kate
Gramins,Todd
Owensby,Jennifer
Shields,Holly
Patrizio,Craig
Jarecki-Smith,Jamie
Bres,Antoinette
Douglass,Mark
Johnston,James
Curry,Norman James
Guidry,Stephen
Nojunas,Tara
Aronson,Lesley
Saba,Valerie
Carten,Tami
Bixler,Kristopher Mark
Vasquez,Jorge
Stephenson,Cassandra
Riega,Adrian Samuel
Jensen,Robert Brian
Winters,Nathan
Rzetelny,Adam
Abdallah,Waleed
Erwin,Jason
Slipp,Megan
Townsend,Shane
Khanna.Karan
Crimeni,Carmela
McGonigal,Lindsey
Cohen,Judith
Ricigliano,Louis Joseph

CONFIDENTAIL

Barbara D. Richardson, Commissioner of Insurance

Non-Resident Producer

Casualty, Property, Surety

WAYNE G MCVAUGH

335A W JEFFERSON ST
MEDIA, PA 19063-3603

is authorized to transact business as described above

License No: 500206 Issue Date: 08-15-2006 Expiration Date: 09-01-2021

Generated by Sircon 172538174

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

WAYNE G MCVAUGH
335A W JEFFERSON ST, MEDIA, PA 19063-3603

LICENSE NUMBER: 500206

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer
Casualty, Property, Surety

Issue Date: 08-15-2006 Expiration Date: 09-01-2021

Generated by Sircon 172538174

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Advanz Pharma (US) Corp

Physical Address: 2801 Lakeside Drive Ste 210, Office 7

City: Bannockburn State: IL Zip: 60015

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 312-279-2325 Website: apus-gmb@advanzpharma.com

Name of Designated Representative (DR): Gail Q. Teves

Licensing Company Email: apus-gmb@advanzpharma.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer Virtual
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		☑
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		☑
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		☑
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		☑
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		☑

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cardinal Health Specialty Pharmaceutical Services
Address: 15 Ingram Boulevard City: La Vergne State: TN Zip: 37086

Name: Gregory Pharmaceutical Holdings, Inc. (dba UPM Pharmaceuticals Inc.)
Address: 501 Fifth Street City: Bristol State: TN Zip: 37620

Name: Patheon Manufacturing Services LLC
Address: 5900 Martin Luther King Jr. Hwy City: Greenville State: NC Zip: 27834

Name: Anesta LLC
Address: 4745 Wiley Post Way City: Salt Lake City State: UT Zip: 84116

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Advanz Pharma Corp Limited
Corporation/Organization Name: Advanz Pharma (US) Corp
Mailing Address: 2801 Lakeside Drive Ste 210, Office 7
City: Bannockburn State: IL Zip: 60015
Telephone: 312-279-2325 Email: apus-gmb@advanzpharma.com
Contact Person Name: Gail Q. Teves

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Advanz Pharma (US) Corp

Facility Name

John Lawrence Miles III (Larry Miles)

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

18 June 2024

Date

Board Use Only	Date Received: _____	Amount: _____

National Drug Code Directory

Current through April 19, 2024

You have searched Finished drug products

Search Results: *'concordia'*

Back to Search Page () | Search Again ()

CSV Excel

Display All **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketi Date
+ Dibenzyline	59212-001-01	10 mg/1	CAPSULE	ORAL	NDA008708	Concordia Pharmaceuticals Inc.	59212-001	Phenoxybenzamine Hydrochloride	PHENOXYBENZAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/26/19
+ Dibenzyline	59212-001-02	10 mg/1	CAPSULE	ORAL	NDA008708	Concordia Pharmaceuticals Inc.	59212-001	Phenoxybenzamine Hydrochloride	PHENOXYBENZAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/20
+ Donnatal	59212-423-04	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-423	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-425-04	.0194 mg/1, .1037 mg/1, 16.2 mg/1, .0065 mg/1	TABLET	ORAL		Concordia Pharmaceuticals Inc.	59212-425	PHENOBARBITAL, HYOSCYAMINE SULFATE, ATROPINE SULFATE, SCOPOLAMINE HYDROBROMIDE	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-423-16	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-423	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-425-10	.0194 mg/1, .1037 mg/1, 16.2 mg/1, .0065 mg/1	TABLET	ORAL		Concordia Pharmaceuticals Inc.	59212-425	PHENOBARBITAL, HYOSCYAMINE SULFATE, ATROPINE SULFATE, SCOPOLAMINE HYDROBROMIDE	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-422-04	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-422	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketi Date
+ Donnatal	59212-422-10	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-422	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-422-16	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-422	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Donnatal	59212-423-10	.0194 mg/5mL, .1037 mg/5mL, 16.2 mg/5mL, .0065 mg/5mL	ELIXIR	ORAL		Concordia Pharmaceuticals Inc.	59212-423	phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide	ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL; SCOPOLAMINE HYDROBROMIDE	HUMAN PRESCRIPTION DRUG	12/30/19
+ Dyrenium	59212-002-01	50 mg/1	CAPSULE	ORAL	NDA013174	Concordia Pharmaceuticals Inc.	59212-002	Triamterene	TRIAMTERENE	HUMAN PRESCRIPTION DRUG	10/01/19
+ Dyrenium	59212-003-01	100 mg/1	CAPSULE	ORAL	NDA013174	Concordia Pharmaceuticals Inc.	59212-003	Triamterene	TRIAMTERENE	HUMAN PRESCRIPTION DRUG	01/01/19
+ LANOXIN	59212-249-55	.25 mg/1	TABLET	ORAL	NDA020405	Concordia Pharmaceuticals Inc.	59212-249	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG	09/30/20
+ LANOXIN	59212-242-56	.125 mg/1	TABLET	ORAL	NDA020405	Concordia Pharmaceuticals Inc.	59212-242	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG	09/30/20
+ LANOXIN	59212-240-55	.0625 mg/1	TABLET	ORAL	NDA020405	Concordia Pharmaceuticals Inc.	59212-240	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG	09/30/20
+ LANOXIN	59212-242-55	.125 mg/1	TABLET	ORAL	NDA020405	Concordia Pharmaceuticals Inc.	59212-242	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG	09/30/20
+ Nilandron	59212-111-14	150 mg/1	TABLET	ORAL	NDA020169	Concordia Pharmaceuticals Inc.	59212-111	Nilutamide	NILUTAMIDE	HUMAN PRESCRIPTION DRUG	07/15/20
+ Orapred	59212-700-12	10 mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA021959	Concordia Pharmaceuticals Inc.	59212-700	prednisolone sodium phosphate	PREDNISOLONE SODIUM PHOSPHATE	HUMAN PRESCRIPTION DRUG	06/30/20

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketi Date
+ Orapred	59212-701-12	15 mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA021959	Concordia Pharmaceuticals Inc.	59212-701	prednisolone sodium phosphate	PREDNISOLONE SODIUM PHOSPHATE	HUMAN PRESCRIPTION DRUG	06/30/20
+ Orapred	59212-702-12	30 mg/1	TABLET, ORALLY DISINTEGRATING	ORAL	NDA021959	Concordia Pharmaceuticals Inc.	59212-702	prednisolone sodium phosphate	PREDNISOLONE SODIUM PHOSPHATE	HUMAN PRESCRIPTION DRUG	06/30/20
+ PANRETIN	59212-601-22	60 mg/60g	GEL	TOPICAL	NDA020886	Concordia Pharmaceuticals Inc.	59212-601	alitretinoin	ALITRETINOIN	HUMAN PRESCRIPTION DRUG	09/10/20
+ PARNATE	59212-447-10	10 mg/1	TABLET, FILM COATED	ORAL	NDA012342	Concordia Pharmaceuticals Inc.	59212-447	tranylcypromine sulfate	TRANYLCYPROMINE SULFATE	HUMAN PRESCRIPTION DRUG	01/14/20
+ Plaquenil	59212-562-10	200 mg/1	TABLET	ORAL	NDA009768	Concordia Pharmaceuticals Inc.	59212-562	Hydroxychloroquine Sulfate	HYDROXYCHLOROQUINE SULFATE	HUMAN PRESCRIPTION DRUG	06/28/20
+ Plaquenil	59212-562-11	200 mg/1	TABLET	ORAL	NDA009768	Concordia Pharmaceuticals Inc.	59212-562	Hydroxychloroquine Sulfate	HYDROXYCHLOROQUINE SULFATE	HUMAN PRESCRIPTION DRUG	08/10/20
+ Plaquenil	59212-562-60	200 mg/1	TABLET	ORAL	NDA009768	Concordia Pharmaceuticals Inc.	59212-562	Hydroxychloroquine Sulfate	HYDROXYCHLOROQUINE SULFATE	HUMAN PRESCRIPTION DRUG	01/05/20
+ Salagen	59212-705-10	5 mg/1	TABLET, FILM COATED	ORAL	NDA020237	Concordia Pharmaceuticals Inc.	59212-705	Pilocarpine Hydrochloride	PILOCARPINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/20
+ Salagen	59212-775-10	7.5 mg/1	TABLET, FILM COATED	ORAL	NDA020237	Concordia Pharmaceuticals Inc.	59212-775	Pilocarpine Hydrochloride	PILOCARPINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/20
+ Uroxatral	59212-200-30	10 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA021287	Concordia Pharmaceuticals Inc.	59212-200	Alfuzosin HCl	ALFUZOSIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/18/20
+ Uroxatral	59212-200-10	10 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA021287	Concordia Pharmaceuticals Inc.	59212-200	Alfuzosin HCl	ALFUZOSIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/03/20
+ Zonegran	59212-681-10	25 mg/1	CAPSULE	ORAL	NDA020789	Concordia Pharmaceuticals Inc.	59212-681	Zonisamide	ZONISAMIDE	HUMAN PRESCRIPTION DRUG	03/27/20
+ Zonegran	59212-680-10	100 mg/1	CAPSULE	ORAL	NDA020789	Concordia Pharmaceuticals Inc.	59212-680	Zonisamide	ZONISAMIDE	HUMAN PRESCRIPTION DRUG	03/27/20

Showing 1 to 31 of 31 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment to Advanz Pharma (US) Corp Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations:
Advanz Pharma (US) Corp ("Advanz Pharma") is a specialty pharmaceutical company selling non-controlled prescription drugs to other wholesalers. Advanz Pharma is a virtual wholesaler/manufacturer using contract third-party logistics (3PL) providers. As a result, no product is manufactured, stored or distributed at the, IL, location.

The IL, Hours of operation are Monday – Friday from 9:00 a.m. to 5:00 p.m.

Advanz Pharma (US) Corp Directors and employees

Name	Title	Residence Address	Ownership %
John Lawrence Miles III (Larry Miles)	President	[redacted]	0%
Robert Ford	Director	[redacted]	0%

Designated Rep:
Gail Q. Teves, U.S. Operations Manager
[redacted]

Parent Company:
Advanz Pharma Corp Limited (100%)
11-15 Seaton Place,
St Helier, Jersey, JE4 0QH

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ADVANZ PHARMA (US) CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ADVANZ PHARMA (US) CORP." WAS INCORPORATED ON THE SIXTEENTH DAY OF APRIL, A.D. 2013.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5319733 8300

SR# 20243516747

Authentication: 204244530

Date: 08-26-24

You may verify this certificate online at corp.delaware.gov/authver.shtml



State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005448

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED WHOLESALE DRUG DISTRIBUTOR

WHOLESALE DRUG

ADVANZ PHARMA (US) CORP.
GAIL Q TEVES
2801 LAKESIDE DR STE 210 OFFICE 7
BANNOCKBURN, IL 60015-1200

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

19209267

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4714461

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
Advanz Pharma (US) Corp.	Bannockburn, IL 60015	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005448	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	04/09/2024	04/09/2024	12/31/2024	N

Generated on: 6/6/2024 9:03:54 AM

Wells Fargo Bank, N.A.
U.S. Standby Trade Operations
1525 W W.T. Harris Blvd., CIC-3C2
MAC D1109-012
Charlotte, NC 28262
Phone: 1 (800) 776-3862, Option 2
E-Mail: StandbyCustomerCare@wellsfargo.com

Irrevocable Standby Letter Of Credit

Number : IS000458655U
Issue Date : May 28, 2024

BENEFICIARY	APPLICANT
NEVADA STATE BOARD OF PHARMACY 555 DOUBLE EAGLE COURT #1100 RENO, NEVADA 89521-8991	ADVANZ PHARMA (US) CORP 2801 LAKESIDE DRIVE STE 210 OFFICE 7, BANNOCKBURN CHICAGO, ILLINOIS 60015

LETTER OF CREDIT ISSUE AMOUNT USD 25,000.00 EXPIRY DATE MAY 31, 2025

LADIES AND GENTLEMEN:

WE HAVE BEEN INFORMED, BUT DO NOT INDEPENDENTLY VERIFY, THAT THIS LETTER OF CREDIT IS BEING ISSUED IN LIEU OF A PERFORMANCE GUARANTEE IN REFERENCE TO APPLYING LICENSE TO SUPPLY PHARMACEUTICAL PRODUCTS COLLECTIVELY KNOWN AS AGREEMENT, BY AND BETWEEN. NEVADA STATE BOARD OF PHARMACY (THE "BENEFICIARY") AND ADVANZ PHARMA (US) CORP (THE "APPLICANT"), IN THE AMOUNT OF USD25,000.00 (USD TWENTY-FIVE THOUSAND AND 00/100) REPRESENTING 100 PERCENT OF THE AGREEMENT.

THEREFORE, IN CONSIDERATION OF ABOVE, WE, WELLS FARGO BANK, N.A., 1525 W. W.T. HARRIS BLVD., MAC: D1109-012, CHARLOTTE, NC 28262, ATTN: US TRADE SERVICES, STANDBY LETTERS OF CREDIT, AT THE REQUEST AND FOR THE ACCOUNT OF THE ABOVE REFERENCED APPLICANT, WE HEREBY ISSUE OUR IRREVOCABLE STANDBY LETTER OF CREDIT IS000458655U (THE "WELLS CREDIT") IN YOUR FAVOR IN THE AMOUNT OF (USD TWENTY-FIVE THOUSAND AND 00/100) (USD25,000.00) AVAILABLE WITH US AT OUR ABOVE OFFICE BY PAYMENT AGAINST PRESENTATION OF THE FOLLOWING DOCUMENTS:

A DRAFT DRAWN ON US AT SIGHT MARKED "DRAWN UNDER WELLS FARGO BANK, N.A. STANDBY LETTER OF CREDIT NO. IS000458655U."

THE ORIGINAL OF THIS STANDBY LETTER OF CREDIT AND ANY AMENDMENTS THERETO.

BENEFICIARY'S SIGNED AND DATED STATEMENT WORDED AS FOLLOWS (WITH THE INSTRUCTIONS IN BRACKETS THEREIN COMPLIED WITH):
NEVADA STATE BOARD OF PHARMACY ("BENEFICIARY") HEREBY DEMANDS US (INSERT AMOUNT OF DRAWING) UNDER WELLS FARGO BANK LETTER OF CREDIT NO. IS000458655U AND CERTIFIES THAT THE AMOUNT DRAWN REPRESENTS THE UNPAID OBLIGATIONS OF ADVANZ PHARMA (US) CORP ("APPLICANT") RELATED TO DEFAULT UNDER THE AGREEMENT DATED (INSERT DATE OF AGREEMENT) BETWEEN THE APPLICANT AND THE BENEFICIARY".

WELLS FARGO

Wells Fargo Bank, N.A.
U.S. Standby Trade Operations
1525 W W.T. Harris Blvd., CIC-3C2
MAC D1109-012
Charlotte, NC 28262
Phone: 1 (800) 776-3862, Option 2
E-Mail: StandbyCustomerCare@wellsfargo.com

PRESENTATION OF DRAWING.
ISSUING BANKS LOCATION. AT THE ADDRESS STIPULATED IN THIS LETTER OF CREDIT. FAX PRESENTATION. DRAWINGS MAY ALSO BE PRESENTED TO US BY FACSIMILE TRANSMISSION TO FACSIMILE NUMBER 844-879-5593 (EACH SUCH DRAWING, A "FAX DRAWING") PROVIDED, HOWEVER, THAT A FAX DRAWING WILL NOT BE EFFECTIVELY PRESENTED UNTIL YOU CONFIRM BY TELEPHONE OUR RECEIPT OF SUCH FAX DRAWING BY CALLING US AT TELEPHONE NUMBER 1-800-776-3862, OPTION 2. IF YOU PRESENT A FAX DRAWING UNDER THIS LETTER OF CREDIT YOU DO NOT NEED TO PRESENT THE ORIGINAL OF ANY DRAWING DOCUMENTS, AND IF WE RECEIVE ANY SUCH ORIGINAL DRAWING DOCUMENTS THEY WILL NOT BE EXAMINED BY US. IN THE EVENT IF A FULL OR FINAL DRAWING THE ORIGINAL LETTER OF CREDIT MUST BE SURRENDERED FOR PROPER DISPOSITION AND TO REMOVE IT FROM CIRCULATION.

THIS STANDBY LETTER OF CREDIT EXPIRES AT OUR COUNTERS ON MAY 31, 2025.

THIS STANDBY IT IS A CONDITION OF THIS LETTER OF CREDIT THAT SUCH EXPIRATION DATE SHALL BE DEEMED AUTOMATICALLY EXTENDED, WITHOUT WRITTEN AMENDMENT, FOR ONE YEAR PERIODS TO MAY 31 IN EACH SUCCEEDING CALENDAR YEAR, UNLESS AT LEAST 30 DAYS PRIOR TO SUCH EXPIRATION DATE WE SEND WRITTEN NOTICE TO YOU VIA COURIER THAT WE ELECT NOT TO EXTEND THE EXPIRATION DATE OF THIS LETTER OF CREDIT BEYOND THE DATE SPECIFIED IN SUCH NOTICE. ANY REFERENCE TO A FINAL EXPIRATION DATE DOES NOT IMPLY THAT WE ARE OBLIGATED TO EXTEND THE EXPIRATION DATE BEYOND THE INITIAL OR ANY EXTENDED DATE THEREOF.

UPON OUR SENDING YOU SUCH NOTICE OF THE NON-EXTENSION OF THE EXPIRATION DATE OF THIS LETTER OF CREDIT, YOU MAY ALSO DRAW UNDER THIS LETTER OF CREDIT, ON OR BEFORE THE EXPIRATION DATE SPECIFIED IN SUCH NOTICE, BY PRESENTATION OF YOUR SIGNED AND DATED DEMAND(S) WORDED AS FOLLOWS WITH THE INSTRUCTIONS IN BRACKETS THEREIN COMPLIED WITH:
"NEVADA STATE BOARD OF PHARMACY (THE "BENEFICIARY") HEREBY DEMANDS US (INSERT AMOUNT OF DRAWING) UNDER WELLS FARGO BANK, N.A. LETTER OF CREDIT NO. IS000458655U (THE "WELLS CREDIT") AND CERTIFIES THAT THE NEVADA STATE BOARD OF PHARMACY HAS RECEIVED WRITTEN NOTIFICATION FROM WELLS FARGO BANK, N.A. THAT THE EXPIRATION DATE OF THE WELLS CREDIT WILL NOT BE EXTENDED FOR ANY ADDITIONAL PERIOD AND, AS OF THE DATE OF THIS DEMAND, NEVADA STATE BOARD OF PHARMACY HAS NOT RECEIVED A LETTER OF CREDIT OR OTHER INSTRUMENT ACCEPTABLE TO NEVADA STATE BOARD OF PHARMACY TO BACK THE OBLIGATIONS OF ADVANZ PHARMA (US) CORP TO NEVADA STATE BOARD OF PHARMACY."

IN THE EVENT OF PARTIAL DRAWINGS WHERE MULTIPLE DRAWINGS ARE NOT PROHIBITED, WELLS FARGO BANK, N.A. SHALL ENDORSE THE ORIGINAL OF THIS LETTER OF CREDIT AND RETURN IT TO THE BENEFICIARY.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO AN ACCOUNT WITH US OR AT ANOTHER BANK, WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS AS THAT OF THE BENEFICIARY'S WITHOUT ANY FURTHER VALIDATION.

ALL BANK CHARGES ARE FOR THE APPLICANTS ACCOUNT.

ALL CORRESPONDENCE AND DEMANDS MADE HEREUNDER MUST BE PRESENTED TO WELLS FARGO BANK, N.A. OFFICE LOCATED AT,1525 W W.T. HARRIS BLVD., MAC: D1109-012, CHARLOTTE, NC 28262, ATTENTION: US TRADE SERVICES, STANDBY LETTERS OF CREDIT.

Wells Fargo Bank, N.A.
U.S. Standby Trade Operations
1525 W W.T. Harris Blvd., CIC-3C2
MAC D1109-012
Charlotte, NC 28262
Phone: 1 (800) 776-3862, Option 2
E-Mail: StandbyCustomerCare@wellsfargo.com

CANCELLATION PRIOR TO EXPIRATION: YOU MAY RETURN THIS LETTER OF CREDIT TO US FOR CANCELLATION PRIOR TO ITS EXPIRATION PROVIDED THAT THIS LETTER OF CREDIT IS ACCOMPANIED BY YOUR WRITTEN AGREEMENT TO ITS CANCELLATION.SUCH WRITTEN AGREEMENT TO CANCELLATION SHOULD SPECIFICALLY REFERENCE THIS LETTER OF CREDIT BY NUMBER, CLEARLY INDICATE THAT IT IS BEING RETURNED FOR CANCELLATION AND BESIGNED BY A PERSON IDENTIFYING THEMSELVES AS AUTHORIZED TO SIGN FOR YOU.

WE HEREBY ENGAGE WITH YOU THAT EACH DRAFT DRAWN UNDER AND IN COMPLIANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT WILL BE DULY HONORED IF PRESENTED TOGETHER WITH THE DOCUMENTS SPECIFIED IN THIS LETTER OF CREDIT TO US ON OR BEFORE THE ABOVE STATED EXPIRY DATE, OR ANY EXTENDED EXPIRY DATE IF APPLICABLE.

THIS LETTER OF CREDIT SETS FORTH IN FULL THE TERMS OF OUR UNDERTAKING, AND SUCH UNDERTAKING SHALL NOT IN ANY WAY BE MODIFIED, AMENDED OR AMPLIFIED BY REFERENCE TO ANY NOTE, DOCUMENT, INSTRUMENT, STATUTE, REGULATION OR AGREEMENT REFERRED TO HEREIN OR IN WHICH THIS LETTER OF CREDIT IS REFERRED TO OR TO WHICH THIS LETTER OF CREDIT RELATES AND ANY SUCH REFERENCE SHALL NOT BE DEEMED TO INCORPORATE HEREIN BY REFERENCE ANY NOTE, DOCUMENT, INSTRUMENT, STATUTE, REGULATION, OR AGREEMENT, OTHER THAN THE STIPULATED ICC RULES AND GOVERNING LAWS.

EXCEPT AS OTHERWISE EXPRESSLY STATED HEREIN, THIS STANDBY LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICE 1998, INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 590.

Very Truly Yours,

WELLS FARGO BANK, N.A.

By: _____
Authorized Signature

The original of the Letter of Credit contains an embossed seal over the Authorized Signature.

Please direct any written correspondence or inquiries regarding this Letter of Credit, always quoting our reference number, to **Wells Fargo Bank, National Association,** Attn: U.S. Standby Trade Services

at 1525 W W.T. Harris Blvd., CIC-3C2
MAC D1109-012
Charlotte, NC 28262

Phone inquiries regarding this credit should be directed to our Standby Customer Connection Professionals

1-800-776-3862 Option 2
(Hours of Operation: 8:00 a.m. ET to 5:00 p.m. PT)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Advanz Pharma (US) Corp

Pharmacy/Wholesaler License # (if applicable): Applying

Physical Address: 2801 Lakeside Drive Ste 210, Office 7,

City: Bannockburn State: IL Zip: 60015

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: 312-279-2325 Website: https://www.advanzpharma.com/

Licensing Company Email: apus-gmb@advanzpharma.com

Section 2: Personal Information

First: Gail Middle: Q. Last: Teves

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐M ☑F ☐X

Mailing Address: 758 Westbury Drive, #2514

City: Cary State: IL Zip: 60013

Telephone: 312-279-2325 Email: [redacted]

Are you a citizen of the United States? ☑Yes ☐No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓ NK

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023-present	[redacted]	[redacted]	IL	60013
From - To (MM/YY – MM/YY)			State	Zip
2003 -6/2023			IL	60169
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Advanz Pharma U.S. Corp			06/2023 - present	
Business Address		**City**	**State**	**Zip**
2801 Lakeside Drive Ste 210, Office 7,		Bannockburn	IL	60015
Phone	**Title**		**Number of Employed Hours**	
312-279-2325	Operations Manager		~2080	

Description of Duties
Overall responsible for the sourcing, distribution, tracking and record-keeping associated with all Advanz Pharma U.S. Corp.'s operations in the United States. Ensures continuous uninterrupted supply of pharmaceutical finished products to all supported markets by providing supply chain management and operational support.

Business Name			From - To (MM/YY – MM/YY)	
Baxter Healthcare Corp			03/2020 - 06/2023	
Business Address		**City**	**State**	**Zip**
1 Baxter Pkwy, Deerfield		Deerfield	IL	60015
Phone	**Title**		**Number of Employed Hours**	
224-948-2000	Operations and Vendor Management PM		~6720	

Description of Duties
Accountable for identifying, documenting, updating, and executing operational processes between external medical writing vendors/internal medical writing team and Baxter functional groups. Streamline processes through the creation of business process diagrams and flow charts. Initiated and formalized vendor effectiveness metrics by defining parameters on deliverables quality, customer engagement, and on-time completion.

Business Name			From - To (MM/YY – MM/YY)	
Elkay Manufacturing Company			11/2019 - 04/2020	
Business Address		**City**	**State**	**Zip**
1333 Butterfield Road, Suite 200		Downers Grove	IL	60515
Phone	**Title**		**Number of Employed Hours**	
630-574-8484	Project Management Consultant		~960	

Description of Duties
Effectively implemented business process mapping guide with the introduction of SIPOC methodology as a baseline. Effectively defined and implemented Project Management Vendor Strategic Partnership project timeline gating templates.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Gail Q. Teves, **certify that as the designated representative for**

Advanz Pharma (US) Corp,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ☑ I am at least 21 years of age;
3. ☑ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ☑ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ☑ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ☑ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ☑ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gail Q. Teves
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gail Q. Teves
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Kane

I, Gail Q. Teves, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/27/2024
Date

Subscribed and Sworn to before me this 27 day of June 2024.

Notary Public Signature

OFFICIAL SEAL
ALBERT FARRANT
Notary Public, State of Illinois
My Commission Expires 03-11-2025

(Seal)

GAIL TEVES, MBA
[redacted]

SUMMARY OF QUALIFICATIONS

Pharma and medical device Operations Project Management leader with a holistic approach to process and/or system improvement, always with a goal to deliver an end-to-end and top-down business solution.

PROFESSIONAL EXPERIENCE

Advanz Pharma U.S. Corp., Bannockburn, IL
An international pharmaceutical company with over 500 employees worldwide whose mission is to help improve the lives of patients globally through the supply of critical medicines.
June 2023-Present

- Operations Manager
  - Overall responsible for the sourcing, distribution, tracking and record-keeping associated with all Advanz Pharma U.S. Corp.'s operations in the United States.
  - Ensures continuous uninterrupted supply of pharmaceutical finished products to all supported markets by providing supply chain management and operational support.
  - Coordinate cross functional activities to resolve any hurdles to the supply of product into all supported markets.
  - Ensure commercial and trade managers in all supported markets are always fully on all aspects of supply.
  - Assume responsibility for all aspects of operations and supply chain activities in all supported markets.

Baxter Healthcare Corp., Deerfield, IL
A healthcare company with over 50,000 employees around the world and whose mission is to help improve and personalize healthcare through meaningful innovations.
April 2020 – May 2023
Operations and Vendor Management PM – EU MDR Program (Clinical Evaluation Deliverables) (Contract)
Responsibilities (This role collaborates with a highly matrixed organization):

- Operations
  - Accountable for identifying, documenting, updating, and executing operational processes between external medical writing vendors/internal medical writing team and Baxter functional groups.
  - Streamline processes through the creation of business process diagrams and flow charts
  - Responsible for budget forecasting and spend oversight
  - Collaborate closely with the Quality Management System team to ensure processes developed are policy compliant
- Vendor Management
  - Ensures operational processes align with relevant Baxter Quality Management System (QMS) processes.
  - Accountable for management of external medical writing vendors to ensure vendor and internal medical writing team performance/cost/quality is appropriately managed and expectations are met.
  - Includes creating/managing the customer feedback system (e.g., feedback surveys) and ensuring the information is used for process improvement
  - Responsible for managing vendor Statements of Work (SOWs), vendor invoices, and working with cross-functional team SMEs for appropriate funding sources.

- Accountable for vendor onboarding and training

Accomplishments:

- Established processes and operating mechanisms to effectively engage and work with multiple global vendors.
- Created and monitor KPI reporting, risk identification and mitigation plan for global legal entities/manufacturing sits.
- Instituted soft automation of various manual tools to standardize input
- Created various process maps to clearly define workflow for various aspects of Worldwide Medical Strategy and Delivery group.
- Created an HTML site similar to SharePoint which functions as a one-stop-shop for various documents, process maps, and references for the EU MDR Clinical Deliverables and related activities.
- Initiated and formalized vendor effectiveness metrics by defining parameters on deliverables quality, customer engagement, and on-time completion.
- Created a site navigation training tool and incorporated it into the vendor training curriculum as part of Baxter's training requirement compliance.
- Effectively monitored and managed a $4M OpEx budget for the completion of Clinical Evaluation Deliverables, working with (7) GBUs along with overall program level budget.

Elkay Manufacturing Company, Downers Grove, IL
November 2019 – April 2020
An American-owned company with over 2,600 employees around the globe, a wide array of customer solutions from plumbing, commercial, industrial, retail, and foodservice goods, and services.
Project Management Consultant
Accomplishments:

- Effectively implemented business process mapping guide with the introduction of SIPOC methodology as a baseline.
- Effectively defined and implemented Project Management Vendor Strategic Partnership project timeline gating templates.
- Managed (5) projects concurrent projects with varying nature, size, complexity, and duration, which includes NPDs (new product development).

Fresenius Kabi USA, Bensenville, IL
A global health care company manufacturing pharmaceutical products and medical device technologies with over 35,000 employees worldwide.
March 2016 – May 2019
Operational Excellence Leader/Project Manager - Serialization
Accomplishments:

- Thrived in a high matrix organization. After one year of employment, presented with Certificate of Appreciation along with an out-of-cycle monetary bonus for "outstanding performance and lasting contributions to" THE SERIALIZATION TEAM (US DSCSA [Drug Supply Chain Security Act) of Fresenius Kabi to targeted timelines.
- In (3) years, delivered (4) on time Level 4 ERP SAP WMS customization enhancement projects to meet FDA DSCSA 10-year Track and Trace regulatory requirements. Overall program cost est. at $1.2M.
- Key strategic partner in the development of overall supplier-distribution-wholesaler integration to ensure deliverables are met with holistic oversight and application of agile solution for Track-and Trace (aggregation) eco-system.

- Through Organizational Change Management, effectively communicated negative impact to the supply chain due to misaligned strategic approach to the FDA DSCSA 10-year regulatory requirements.
- Conducted Risk Awareness presentation and training on non-DSCSA compliance and data traceability.

Wistron Mobile Solutions, Rolling Meadows, IL
A subsidiary of global mobile design leader Wistron Corporation, with over 60,000 employees worldwide
December 2012 - September 2015
Business Ops Manager/Project Leader
Accomplishments:

- Led the project development of a proprietary in-house multi-featured software tool for asset inventory management and ISO compliance, saving more than $300,000 in costs on one-time purchases and annual license renewals.
- Ended the first year with the new management under the $35 million budget by delivering accurate, detailed monthly reports to the VP.
- Flawlessly drove the full vendor integration life cycle, from setup through negotiations, maintenance, RFQs, and contracts/agreements review.
- Facilitated 2015 ISO certification readiness by:
  - developing policies and procedures targeting section 7.6 of ISO 9001:2008.
  - enforcing compliance with ISO 9001 calibration standards and protocols for all R&D test fixture purchases.

BlackBerry, Rolling Meadows, IL
One of the world's most renowned developers of handheld and mobile device technology.
October 2010 – December 2012
Operations Specialist – R&D Devices Software Development
Accomplishments:

- Effectively project coordinated for the software Program Manager in project requirements collection for multiple new product development.
- Maintained accurate budget management, forecasting, and reporting.
- Managed monitoring of all project status milestones and timelines.
- Tracked allocations of prototype and beta devices.
- Successfully streamlined asset audits and inventory oversight.

EDUCATION

Lake Forest Graduate School of Management, Schaumburg, IL
MBA – Leadership, June 2015

Roosevelt University, Schaumburg, IL
BS - Business Administration, June 2006

CERTIFICATION and AFFILIATIONS

- Completed PMP Certification Training, 2019
- Certified Lean Six Sigma Green Belt, Chicago Deming Association
- Management Analytics Certificate, Lake Forest Graduate School of Management
- Change Management Certificate, Lake Forest Graduate School of Management
- Strategy & Execution Certificate, Lake Forest Graduate School of Management

- Certified Scrum Master (CSM) expired 11/2018 ~~ scrumalliance.org

COMPUTER SKILLS

- MS Excel, Word, PowerPoint, Visio, Access Database
- Project Management Tools: MS Project, Workfront, familiarity with Agile PLM
- ERP SAP
- SharePoint Administration
- Wiki Administration
- COUPA
- MindManager

Attachment to Advanz Pharma (US) Corp Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Employee List

Larry Miles – General Manager, USA-Established Brands
Robert Ford – General Counsel, North America
Jaclyn Berno – Director or Trade Operations
Gail Teves – Senior Operations Manager

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Coloplast Corp.

Physical Address: 680 E Travelers Trail

City: Burnsville State: MN Zip: 55337

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 612-337-7800 Website: https://www.coloplast.us

Name of Designated Representative (DR): Gopaul Lall

Licensing Company Email: [redacted] DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - Coloplast Corp. does not distribute drugs or controlled substances.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Coloplast A/S

Corporation/Organization Name: Coloplast Corp.

Mailing Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Telephone: 612-337-7800 Email: [redacted]

Contact Person Name: VP/General Counsel, Stephen Froehle

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration Enclosed 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Enclosed	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** Noted in cover letter		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Enclosed	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Noted in cover letter		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Enclosed	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Enclosed	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Coloplast Corp.

Facility Name

Stephen G. Froehle

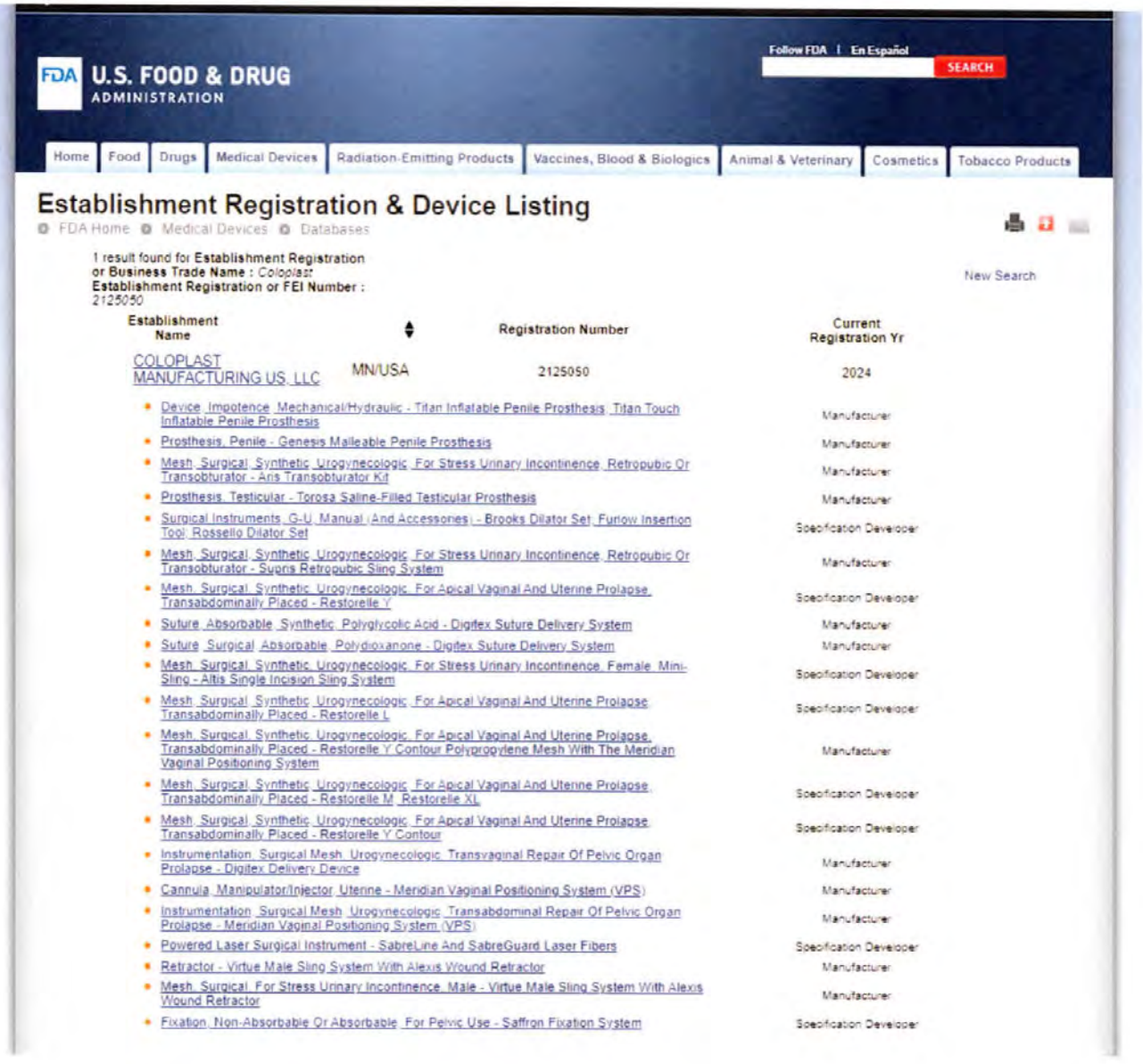
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/28/2024

Date

Board Use Only	Date Received: 9/5/24	Amount: $1000-cc



FDA U.S. FOOD & DRUG ADMINISTRATION

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SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Establishment Registration or Business Trade Name :** *Coloplast*
Establishment Registration or FEI Number : *2125050*

New Search

Establishment Name		Registration Number	Current Registration Yr
COLOPLAST MANUFACTURING US, LLC	MN/USA	2125050	2024

- Device, Impotence, Mechanical/Hydraulic - Titan Inflatable Penile Prosthesis; Titan Touch Inflatable Penile Prosthesis — Manufacturer
- Prosthesis, Penile - Genesis Malleable Penile Prosthesis — Manufacturer
- Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator - Aris Transobturator Kit — Manufacturer
- Prosthesis, Testicular - Torosa Saline-Filled Testicular Prosthesis — Manufacturer
- Surgical Instruments, G-U, Manual (And Accessories) - Brooks Dilator Set; Furlow Insertion Tool; Rossello Dilator Set — Specification Developer
- Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator - Supris Retropubic Sling System — Manufacturer
- Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed - Restorelle Y — Specification Developer
- Suture, Absorbable, Synthetic, Polyglycolic Acid - Digitex Suture Delivery System — Manufacturer
- Suture, Surgical, Absorbable, Polydioxanone - Digitex Suture Delivery System — Manufacturer
- Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-Sling - Altis Single Incision Sling System — Specification Developer
- Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed - Restorelle L — Specification Developer
- Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed - Restorelle Y Contour Polypropylene Mesh With The Meridian Vaginal Positioning System — Manufacturer
- Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed - Restorelle M, Restorelle XL — Specification Developer
- Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed - Restorelle Y Contour — Specification Developer
- Instrumentation, Surgical Mesh, Urogynecologic, Transvaginal Repair Of Pelvic Organ Prolapse - Digitex Delivery Device — Manufacturer
- Cannula, Manipulator/Injector, Uterine - Meridian Vaginal Positioning System (VPS) — Manufacturer
- Instrumentation, Surgical Mesh, Urogynecologic, Transabdominal Repair Of Pelvic Organ Prolapse - Meridian Vaginal Positioning System (VPS) — Manufacturer
- Powered Laser Surgical Instrument - SabreLine And SabreGuard Laser Fibers — Specification Developer
- Retractor - Virtue Male Sling System With Alexis Wound Retractor — Manufacturer
- Mesh, Surgical, For Stress Urinary Incontinence, Male - Virtue Male Sling System With Alexis Wound Retractor — Manufacturer
- Fixation, Non-Absorbable Or Absorbable, For Pelvic Use - Saffron Fixation System — Specification Developer

COLOPLAST CORP.
CORPORATE GOVERNANCE SUMMARY

Coloplast Corp.

Directors:

Henrik Deneke
Manu Varma
Thomas NP Johns, Jr.

Officers:

Manu Varma, Chief Executive Officer
Thomas NP Johns, Jr., Vice President
Kimberly Ditter, Vice President
Shelley Mueller, Treasurer
Stephen G. Froehle, Secretary

✔ Facility

✔ Products Listing

Registration Confirmation

Facility: Coloplast Manufacturing US LLC, Burnsville, Minnesota, UNITED STATES

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2025. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2025 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (mailto:reglist@cdrh.fda.gov).

The Owner/Operator Number for this Registration is: 8010144

Facility Information

Registration Number:

Initial Importer:
N

Facility Name:
Coloplast Manufacturing US LLC

Legal Name:

Address:
680 E Travelers Trl Ste 800,
Burnsville, Minnesota, 55337, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:
N

Owner/Operator Information

Owner/Operator Number:
8010144

Contact Name:
Brian E Schmidt

Company:
COLOPLAST CORP.

Address: 1601 West River Road North
Minneapolis, MINNESOTA, 55411, UNITED STATES

Telephone:
1 - 612 - 8651177

Fax:
-

E-mail: [redacted]

DUNS Number:

Official Correspondent Information

Contact Name:
Brian E Schmidt

Company:
COLOPLAST CORP.

Address: 1601 West River Road North
Minneapolis, MINNESOTA, 55411, UNITED STATES

Telephone:
1 - 612 - 8651177

Fax:
-

E-mail: [redacted]

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D319695	K173501		PWK	Instrumentation, surgical mesh, urogynecologic, transabdominal repair of pelvic organ prolapse	Repackager/Relabeler
			LKF	Cannula, manipulator/injector, uterine	

Date of Initial Registration: Mon Oct 21 14:12:41 EDT 2024

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COLOPLAST CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2024.

Jeffrey W. Bullock, Secretary of State

4408961 8300

SR# 20243503311

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204237106

Date: 08-26-24

MINNESOTA BOARD OF PHARMACY

Profile

Name	Coloplast Manufacturing US, LLC	Address	1940 Commerce Drive P.O. Box 8300 North Mankato, MN 56002-8300

Licenses

Manufact Expired as of 06/21/2010	Type	Manufacturer	Number	459889
	Issue Date	06/16/1993	Expire Date	05/31/2008
Manufact Active as of 06/08/2023	Type	Manufacturer	Number	460281
	Issue Date	06/16/1993	Expire Date	05/31/2025

Public Actions

No items to display

This information is valid as of: Wednesday, August 28, 2024 5:00:15 PM. The licensure data on this website is provided and controlled by the Minnesota Board of Pharmacy. Licensure information is updated as changes to status occur, is secure and considered primary source for verification of a Minnesota license.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/15/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400
Attn: Minneapolis.CertRequest@marsh.com Fax 212-948-0114

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : XL Insurance America, Inc.	24554
INSURER B : The Travelers Indemnity Company	25658
INSURER C : Phoenix Insurance Company	25623
INSURER D : QBE Specialty Insurance Company	11515
INSURER E :	
INSURER F :	

INSURED
Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411

COVERAGES **CERTIFICATE NUMBER:** CHI-010222370-28 **REVISION NUMBER:** 0

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			US00011271LI24A	10/01/2024	10/01/2025	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR			SIR: See Attached			DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY			810-2G274522-24-I2	10/01/2024	10/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			UB-0L995403-24-I2-G	10/01/2024	10/01/2025	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y	N/A					E.L. EACH ACCIDENT	$	1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
D	CYBER LIABILITY			QPL0769038	10/01/2024	10/01/2025	EACH OCCURRENCE		1,000,000
	(Claims Made)			SIR Value: $10,000,000			AGGREGATE		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER
Coloplast Corp.
1601 W. River Road
Minneapolis, MN 55411

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Coloplast Corp. 1601 West River Road Minneapolis, MN 55411
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

GENERAL LIABILITY SIR
$73,850 (500,000 DKK) per claim - non implant products and premises
$1,477,000 (10m DKK) per claim - all implants products (excluding penile implants)
$1,477,000 (10m DKK) per claimant - penile implants
Program annual SIR aggregate of $3,692,500 (25m DKK) except for the penile implants for which a separate program annual aggregate of $7,385,000 (50m DKK) applies
Non-ranking deductible - each and every claim $5,538 (37,500 DKK)

ADDITIONAL NAMED INSURED
Mpathy Medical Devices
Comfort Medical, LLC
Coloplast Manufacturing US, LLC
Affordable Medical, LLC - CM retro date 5/4/21
Hope Medical Supply, Inc. - CM retro date 3/1/21
Rocky Mountain Medical LLC -CM retro date 1/4/21
Nine Continents Medical Inc - CM retro date 11/2/20
Atos Medical Inc. - CM retro date 04/01/22
Griffin Laboratories - CM retro date 04/01/22
ZI-Med Supply - retro date 6/30/2023
Kerecis - retro date 8/30/2023

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJG3930

Application/License No. _____

Coloplast Manufacturing US, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 680 E Travelers Trail, Burnsville, MN 55337 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1111 Northshore Drive Knoxville, TN 37919 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of August, 2024.

APPLICANT/PRINCIPAL

Coloplast Manufacturing US, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MARSH USA LLC
Agency Code: 20-246454

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Bonnie Rice

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 20BSBJG3930
Naming Coloplast Manufacturing US, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of August 22, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Coloplast Corp — MDEG License # (if applicable): NA

Physical Address: 680 E Travelers Trail

City: Burnsville — State: MN — Zip: 55337

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 763-232-7096 — Website: https://www.coloplast.us/

Licensing Company Email: uslegal@coloplast.com

Section 2: Personal Information

First: Daniel — Middle: Owen — Last: Coughlin

Alias(es, nicknames, name changes, etc.): Dan

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] — State: [redacted] — Zip: 55428

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of St. Thomas		09/16 - 12/21	
Address	City	State	Zip
1000 Lasalle Ave	Minneapolis	MN	55403
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota		09/10 - 05/14	
Address	City	State	Zip
100 Church St SE	Minneapolis	MN	55455
Diploma/Degree obtained, if any			
Bachelors of Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Coon Rapids High School		09/06 - 06/10	
Address	City	State	Zip
2340 Northdale Blvd NW	Coon Rapids	MN	55433
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
NA			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
NA			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/24 - Present	[redacted]	[redacted]	MN	55428
09/23 - 08/24	[redacted]		N/A	2100
08/20 - 08/23	[redacted]		MN	55428
04/19 - 8/20	[redacted]		MN	55413
09/17 - 04/19	[redacted]		MN	55418
09/16 - 08/17	[redacted]		MN	55426
08/14 - 08/16	[redacted]		MN	55414
NA				
NA				
NA				

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Coloplast Corp.			08/22 - Present	
Business Address		**City**	**State**	**Zip**
1601 W River Rd N		Minneapolis	MN	55411
Phone	**Title**		**Number of Employed Hours**	
612-337-7800	Commercial Development Manager		4,160	

Description of Duties

Manage vendor relationships and profitability of medical device product portfolio.
One year assignment in Denmark as a commercial development manager leading key commercial projects.

Business Name			From - To (MM/YY – MM/YY)	
Teleflex Inc.			06/14 - 08/22	
Business Address		**City**	**State**	**Zip**
6401 Sycamore Ln N		Maple Grove	MN	55369
Phone	**Title**		**Number of Employed Hours**	
763-656-4300	Senior Manufacturing Engineer		16,500	

Description of Duties

Owner of manufacturing process, manufacturing layout, and manufacturing readiness for medical device manufacturer.

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Daniel Coughlin, **certify that as the MDEG Administrator for**

Coloplast Corp.,

that I (initial that you have read and meet the following requirements):

1. DC Have a high school diploma or its equivalent;
2. DC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Coughlin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-20-24
Date

Board Use Only	Date Received: 9/5/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Coloplast Corp.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 680 E Travelers Trail

City Burnsville State MN Zip 55337

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 612-337-7800 Website https://www.coloplast.us

Licensing Company Email uslegal@coloplast.com

Section 2: Personal Information

First Gopaul Middle _____ Last Lall

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State MN Zip 55448

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Guyana		10/1987-06/1988	
Address	City	State	Zip
Cummingslodge	East Coast Dem		
Diploma/Degree obtained, if any			
Accounts			

School Name		From - To (MM/YY – MM/YY)	
Georgetown School of Accountancy		06/1981-12/1981	
Address	City	State	Zip
Charlott Street	Georgetown		
Diploma/Degree obtained, if any			
LCC - Bookkeeping - Elementary			

School Name		From - To (MM/YY – MM/YY)	
Georgetown School of Accountancy		01/1980-06/1980	
Address	City	State	Zip
Charlott Street	Georgetown		
Diploma/Degree obtained, if any			
LCC - Bookkeeping - Elementary			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023-Present	[redacted]	[redacted]	MN	55448
11/2021-06/2023			MN	55448
03/2003-11/2021			MN	55434
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Coloplast Corp.			06/2006 - Present	
Business Address		**City**	**State**	**Zip**
1601 West River Road N		Minneapolis	MN	55411
Phone	**Title**		**Number of Employed Hours**	
612-337-7800	Senior Warehouse Lead		37,440	
Description of Duties				
Responsible for distribution and warehouse management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Gopaul Lall, **certify that as the designated representative for**

Coloplast Corp.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GL I am at least 21 years of age;
3. GL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gopaul Lall

Print Name (First, Last)

G Lall

Original Signature (electronic, copies or stamps not accepted)

08/26/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gopaul Lall

Print Name (First, Last)

G Lall

Original Signature (electronic, copies or stamps not accepted)

08/26/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Hennepin

I, Gopaul Lall, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

G Lall

Original Signature

08/26/2024

Date

Subscribed and Sworn to before me this 26th day of August.

Tara Farrington

Notary Public Signature

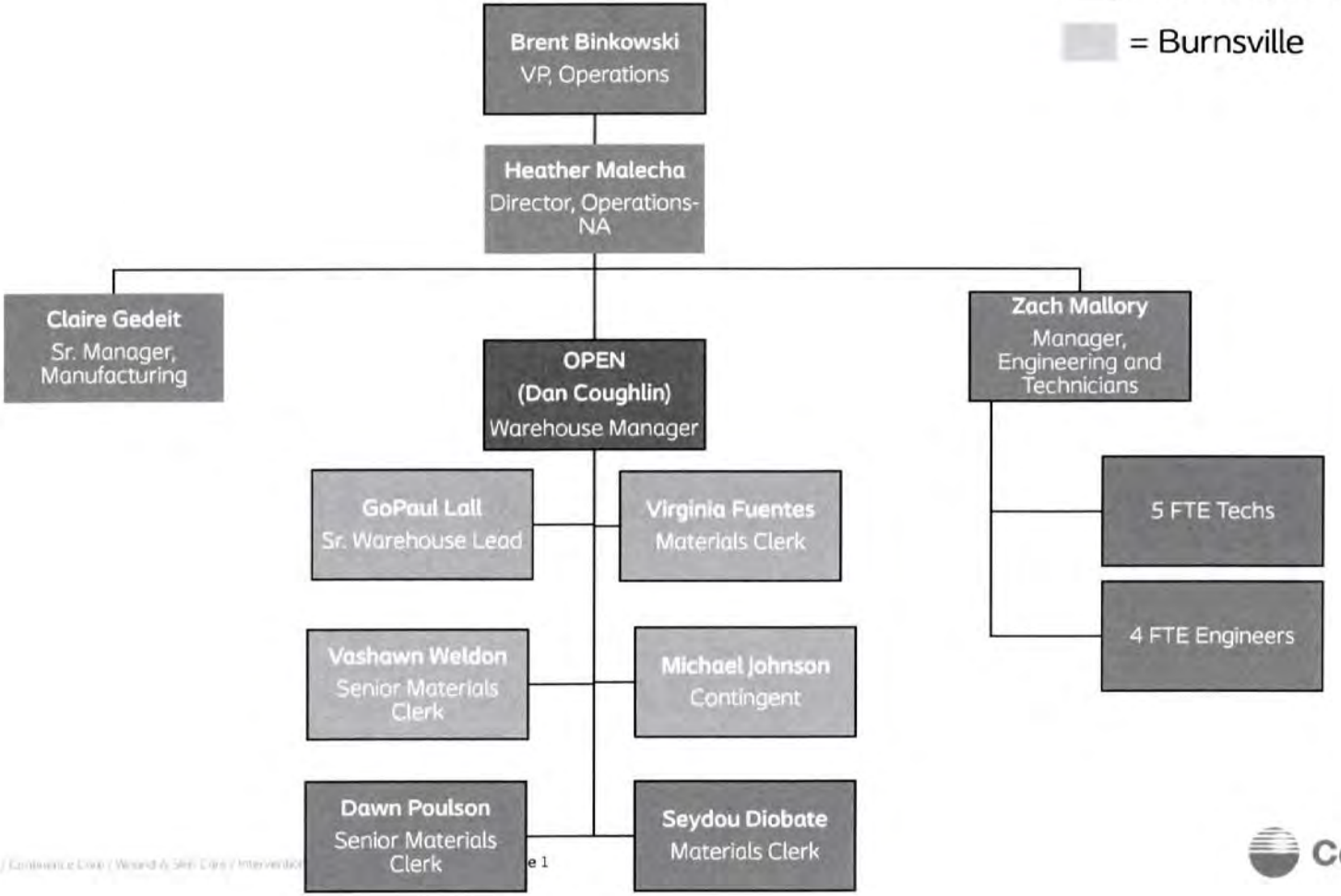
Tara Michele Farrington
Notary Public
Minnesota
My Commission Expires January 31, 2029

(Seal)

Org Chart-Future State Operations

= Minneapolis

= Burnsville



Coloplast

Coloplast

Coloplast has included a list of the management and leadership employees at the Applicant's Minnesota address, rather than listing every involved employee's name and other information in detail. The management and leadership employees that are identified in the MN Application are the only employees who have the power to exercise significant influence on the operation of Applicant's activities at the address set out in this letter. The information in this paragraph may be helpful for Section 9 of the MN Application in bullet 10 ("list containing each employee").

The Personal Record History Record Application described in bullet 7 of MN Application Section 9 is not applicable to Coloplast Corp.

Sincerely,

Aaron Rodriguez
Senior Legal Counsel, North America

Enclosures: Wholesaler Application Package with Payment

4CC

Maria Herrera

FP exempt- per
NAC 639.593 Section 6 (e)

From: Steve Kim <Steve.Kim@intuvie.com>
Sent: Tuesday, October 22, 2024 8:50 AM
To: Maria Herrera
Subject: RE: New wholesale license approval status

Follow Up Flag: Follow up
Flag Status: Flagged

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Maria,

I'd like to clarify the relationship between Intuvie LLC, Zyno Medical LLC and InfuTronix LLC.
The applicant, Intuvie LLC is shipping Zyno Medical's products exclusively to all of clinics including distributors with no restriction.
The manufacturer of the products, Zyno Medical LLC only ships the products to Intuvie LLC. Intuvie LLC does not distribute any products from InfuTronix any longer.

Intuvie LLC, Zyno Medical LLC and InfuTronix LLC are affiliates under the same ownership.

To further clarify, Intuvie LLC is NOT only shipping products to Zyno Medical and InfuTronix.

Hope I answered your question.

Looking forward to hearing from you soon.

Best,
Steve Kim

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, October 22, 2024 11:30 AM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ■ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Intuvie LLC

Physical Address: 177 Pine Street

City: Natick State: MA Zip: 01760

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 508-907-7797 Website: www.intuvie.com

Name of Designated Representative (DR): Junkoo (Steve) Kim

Licensing Company Email: AR@intuvie.com DR Email: steve.kim@intuvie.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zyno Medical LLC

Address: 177 Pine Street City: Natick State: MA Zip: 01760

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 6: Partnership

Partnership Name: Intuvie Holdings LLC

Mailing Address: 177 Pine Street

City: Natick State: MA Zip: 01760

Telephone: 508-907-7797 Email: chang.lee@intuvie.com

Contact Person Name: Changying Lee

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Intuvie LLC

Facility Name

Junkoo Kim

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/23/2024

Date

Board Use Only	Date Received: 8/1/24	Amount: $1000cc

List of Partners and their percent ownership

Owners	%
Changying Lee	30.06%
Chaoyoung Lee	30.07%
Christopher Long Lee 2012 Irrevocable Trust	13.29%
Frederick Lee 2010 Irrevocable Trust	13.29%
Alan Lee 2010 Irrevocable Trust	13.29%
	100.00%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INTUVIE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "INTUVIE LLC" WAS FORMED ON THE SIXTH DAY OF JULY, A.D. 2017.

Jeffrey W. Bullock, Secretary of State

6468360 8300

SR# 20243326852

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204091711

Date: 08-05-24

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MAURA T. HEALEY
Governor

KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary

ROBERT GOLDSTEIN, MD, PhD
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

August 2, 2024

By email to: Steve.kim@intuvie.com

Steve Kim, Senior Director of Finance
Intuvie LLC
177 Pine Street
Natick, Massachusetts 01760

RE: No requirement for registration/licensure with Drug Control Program

To Whom it May Concern:

If you are a manufacturer and/or a distributor **in** Massachusetts and your company does not manufacture, dispense or distribute a controlled substance within the Commonwealth, or possess a controlled substance for such purposes your company does not need, and has no basis for obtaining, a controlled substances registration from Massachusetts.

Also, if you are a manufacturer and/or a distributor **outside** of Massachusetts and your company does not manufacture, dispense or distribute a controlled substance within the Commonwealth, or possess a controlled substance in the Commonwealth for such purposes your company does not need, and has no basis for obtaining, a controlled substances registration from Massachusetts.

Sincerely,

Traci Westgate
Director
Massachusetts Controlled Substance Registration

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/1/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Arthur J. Gallagher Risk Management Services, LLC 470 Atlantic Avenue Boston MA 02210	**CONTACT NAME:** **PHONE (A/C, No, Ext):** 617-261-6700 **FAX (A/C, No):** 617-646-0400 **E-MAIL ADDRESS:**
INSURED ZYNOMED-01 Intuvie LLC 177 Pine Street Natick, MA 01760	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Great American Risk Solutions Surplus Lines Insura — 35351 **INSURER B :** **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 1299247913 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			PLE786456-02	11/15/2023	11/15/2024	EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 500,000
							MED EXP (Any one person)	$ 20,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Additional Named Insureds: Zyno Medical, LLC, Pine 177 RE, LLC, Zyno Solutions LLC, Infulytics LLC

$50,000 Aggregate - Limited Product Withdrawal Expense
Deductible: $2,500 per claim

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Patrick J Veale

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TCS27227

Application/License No. _____

Intuvie LLC, doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

177 Pine St, Natick, MA 01760-1331, as
Address of Applicant/Principal
PRINCIPAL, and Hudson Insurance Company, a
Surety Company
corporation organized under the laws of the state of Delaware
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address

for purposes of service is

8777 N Gainey Center Dr Ste 240, Scottsdale, AZ 85258-2154 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 07/31/2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of July, 20 24.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Alec Kleiner, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

TCS27227

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Alec Kleiner

of the State of Arizona

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars and Zero Cents

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly d, on this 2nd day of June, 20 22 at New York, New York.

: seal)

HUDSON INSURANCE COMPANY

Attest .....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By .....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY NOTARY PUBLIC STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 31st day of July, 20 24

seal)

By .....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Intuvie LLC MDEG License # (if applicable) _____

Physical Address 177 Pine Street

City Natick State MA Zip 01760

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 508-907-7797 Website www.intuvie.com

Licensing Company Email steve.kim@intuvie.com

Section 2: Personal Information

First Junkoo Middle _____ Last Kim

Alias(es, nicknames, name changes, etc.) Steve

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 177 Pine Street

City Natick State MA Zip 01760

Telephone 508-907-7797 Email steve.kim@intuvie.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Suffolk University		09/03-09/10	
Address	City	State	Zip
73 Tremont Street	Boston	MA	02108
Diploma/Degree obtained, if any			
Master degree in taxation for CPA's			

School Name		From - To (MM/YY – MM/YY)	
Yonsei University		03/86-02/90	
Address	City	State	Zip
50 Yonsei-ro, Seodaemun-gu	Seoul	South Kor	03722
Diploma/Degree obtained, if any			
Bachelor degree in Business Adminatration			

School Name		From - To (MM/YY – MM/YY)	
Janghoon High School		03/82-02/85	
Address	City	State	Zip
26 Yeongdeungpo-ro 64-gil, Yeongdeungpo District	Seoul	South Kor	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/05-07/24	[redacted]	Chestnut Hill	MA	02467
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Intuvie LLC and its affiliates			12/11-07/24
Business Address	**City**	**State**	**Zip**
177 Pine Street	Natick	MA	01760
Phone	**Title**	**Number of Employed Hours**	
508-907-7797	Senior Director of Finance	25,400	
Description of Duties			
Supervising operations, customer support, technical support, administration, finance and accounting			

Business Name			From - To (MM/YY – MM/YY)
ETEX Corporation			07/96-11/11
Business Address	**City**	**State**	**Zip**
38 Sidney Street	Cambridge	MA	02139
Phone	**Title**	**Number of Employed Hours**	
NA	Chief Financial Officer	31,000	
Description of Duties			
Supervising operations, sales, human resource, administrations, finance and accounting			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Junkoo Kim, **certify that as the MDEG Administrator for**

Intuvie LLC,

that I (initial that you have read and meet the following requirements):

1. jk Have a high school diploma or its equivalent;
2. jk Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. jk Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. jk Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Junkoo Kim
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/23/2024
Date

Board Use Only	Date Received: 8/12/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Intuvie LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 177 Pine Street

City Natick State MA Zip 01760

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Junkoo Middle _____ Last Kim

Alias(es, nicknames, name changes, etc.) Steve

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 177 Pine Street

City Natick State MA Zip 01760

Telephone [redacted] Email steve.kim@intuvie.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Suffolk University		09/03-09/10	
Address	City	State	Zip
73 Tremond Street	Boston	MA	02108
Diploma/Degree obtained, if any			
Master Degree in taxation for CPA's			

School Name		From - To (MM/YY – MM/YY)	
Yonsei University		03/86-02/90	
Address	City	State	Zip
50 Yonsei-ro, Seodaemun-gu	Seoul	South Kor	03722
Diploma/Degree obtained, if any			
Bachelor degree in Business Adminstation			

School Name		From - To (MM/YY – MM/YY)	
Janghoon High School		03/82-02/85	
Address	City	State	Zip
26 Yeongdeungpo-ro 64-gil, Yeongdeungpo District	Seoul	South Kor	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/05-08/24	[redacted]	Chestnut Hill	MA	02467
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Intuvie LLC and its affiliates			12/11-08/24	
Business Address		**City**	**State**	**Zip**
177 Pine Street		Natick	MA	01760
Phone	**Title**		**Number of Employed Hours**	
508-907-7797	Senior Director of Finance		25,400	
Description of Duties				
Supervising operations, customer service, technical support, adminstration, finance and accouting				

Business Name			From - To (MM/YY – MM/YY)	
ETEX Corporation			07-96-11/11	
Business Address		**City**	**State**	**Zip**
38 Sidney Street		Cambridge	MA	02139
Phone	**Title**		**Number of Employed Hours**	
NA	Chief Financial Officer		31,000	
Description of Duties				
Supervising operations, sales, human resources, admistration, finance and accounting				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Junkoo Kim, **certify that as the designated representative for**

Intuvie LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Junkoo Kim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/8/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Junkoo Kim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/8/2024

Date

Please have this section completed in the presence of a Notary Public.

State of MASS, ss. County of MIDDLESEX

I, Junkoo Kim, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/8/2024

Date

AUG 08 2024

Subscribed and Sworn to before me this 08 day of August 2024.

Notary Public Signature

ARVIND BASIL
My Commission Expires JUNE 21ST, 2030
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Intuvie LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 177 Pine St

City: Natick State: MA Zip: 01760

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 5086552008 Website: www.intuvie.com

Licensing Company Email:

Section 2: Personal Information

First: Chaoyoung Middle: Last: Lee

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Natick State: MA Zip: 01760

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota		1990-1993	
Address	City	State	Zip
	Minneapolis	MN	55455
Diploma/Degree obtained, if any			
PHD in Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Jiaotong University		1986-1989	
Address	City	State	Zip
	Shanghai		
Diploma/Degree obtained, if any			
MS in Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Zhejiang University		1981-1986	
Address	City	State	Zip
	Hangzhou		
Diploma/Degree obtained, if any			
BS in Biomedical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Meishan High School		1978-1981	
Address	City	State	Zip
	Nanjing		
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/11-present	[redacted]	Weston	MA	02493
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TxSphere LLC			01/24-present
Business Address	**City**	**State**	**Zip**
138 Pine St	Natick	MA	01760
Phone	**Title**		
617-515-1637	President/Owner		
Description of Duties			
General management, R&D leadership			

Business Name			From - To (MM/YY – MM/YY)
Five L Capital, Inc and subsidiaries			2003-present
Business Address	**City**	**State**	**Zip**
177 Pine St	Natick	MA	01760
Phone	**Title**		
617-515-1637	Chairman of the board		
Description of Duties			
Corporate governance			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHAOYOUNG LEE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/31/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, CHAOYOUNG LEE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/31/2024

Date

Subscribed and Sworn to before me this 31st day of July, 2024

Notary Public Signature

JUNKOO KIM
Notary Public, Commonwealth of Massachusetts
My Commission Expires February 15, 2030
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Intuvie LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 177 Pine St

City Natick State MA Zip 01760

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 5086552008 Website www.intuvie.com

Licensing Company Email _____

Section 2: Personal Information

First Changying Middle _____ Last Lee

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 177 Pine St

City Natick State MA Zip 01760

Telephone [redacted] Email chang.lee@intuvie.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Suffolk University		1996-2000	
Address	City	State	Zip
73 Tremont St	Boston	MA	02108
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Shanghai Univerity of Finance and Economics		1987-1991	
Address	City	State	Zip
	Shanghai		
Diploma/Degree obtained, if any			
BS in Finance			

School Name		From - To (MM/YY – MM/YY)	
Nanyangmofan High School		19841987	
Address	City	State	Zip
	Shanghai		
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/11-present	[redacted]	Weston	MA	02493
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Five L Capital, Inc and subsidiaries			2005-present
Business Address	**City**	**State**	**Zip**
177 Pine St	Natick	MA	01760
Phone	**Title**		
508-655-9399	Treasurer		
Description of Duties			
Maintain bank relationship, oversee tax filing			

Business Name			From - To (MM/YY – MM/YY)
Pine 177 RE LLC			2012-present
Business Address	**City**	**State**	**Zip**
177 Pine St	Natick	MA	01760
Phone	**Title**		
508-655-9399	Manager		
Description of Duties			
Building Maintenance			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Changying Lee

Print Name (First, Last)

Chi Z Lee

Original Signature (electronic, copies or stamps not accepted)

7/31/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, Changying Lee, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Chi Z Lee

Original Signature

7/31/2024

Date

Subscribed and Sworn to before me this 31st day of July, 2024.

Notary Public Signature

JUNKOO KIM
Notary Public, Commonwealth of Massachusetts
My Commission Expires February 15, 2029

List of employees and consultants

Full name	Position
Aldana, Kenia	Human Resources Generalist
Amin, Zia U	Lead Sr. Systems Administrator
Andrea, Michael W	Complaint Eval Specialist
Armlin, Anthony	Sr Eng, Software Development
Barber, Harlan	Senior Product Manager
Barrett, Bradley G	Senior System Administrator
Benhida, Ahmed	Principal SQA Engineer
Benvenutti, Antonio	Director, Complaint Vigilance
Boddapati, Sandhya N	SW QA Engineer I
Brian Gard	Consultant
Brooks, Julian K	Help Desk Associate
Brown, George A	CAPA Lead
Buchan, David D	Dev/Ops Engineer
Buckley, Heather M	VP of QA
Burgess, Kenneth A	Shipping and Receiving Clerk
Butler, Dakotah E	Application Specialist
Caisse, Evan M	Complaint Eval Specialist
Caldwell, Colleen M	Accounting Supervisor
Castillo Quiroz, Alberto L	DBA
Charles, Robert	Director, HW Engineering
Chen, Chaofan	Principal Mechanical Engineer
Chen, Shiyu	Engineer II - Mechanical Eng
Chen, Ziqi	Software Engineer
Chennapolla, Swapna	Senior Network Engineer
Choi, Ok	Technician
Chris Crowley	Chief Information Officer
Crowley, Chris	Chief Information Officer
Custodio Mercedes, Sylvia	Document Control Specialist
D'Lima, Adrian F	Director, Systems Engineering
DeJesus, Melisa	Customer Service Coordinator
Dubinsky, Boris D	Principal VandV Lead Engineer
Dudkiewicz, Joseph D	Technician
Dunham, Todd D	Sales Solutions Specialist
Fisher Jr, Paul	System Administrator
Fisher, Paul	Technical Operations Mgr
Fitton, Lori A	RA Operations Manager
Flynn, David M	Senior Manager-Prog Mgmt
Foster, Gary F	VP of Business Development
Francoeur, Leo V	Information Security Analyst

Frank, David A	Principal SQA Engineer
Gao, Jie	Sr Eng, Software Quality
Gauzza, Marcus	Application Specialist
Grey, Charles	Clinical App Specialist
Guzman, Miranda	Complaint Handling Specialist
Hardesty, Matthew T	Senior SW QA Engineer
Harrison, Thomas W	Senior System Administrator
Hatch, Benjamin	Business Analyst
Hopkins, Thomas J	VP of Medical Affairs
Howe, Thomas J	VP of Finance
Huang, Di	Principal SW Engineer Manager
Jackan, Adrian	Serv & Maint Ops Supervisor
Jacob, Ariel Tharayil	Design Quality Manager
Juckett, Teri L	Regulatory Fellow
Kelley-Hoffman, Christopher M	Software Engineer
Kennel, Lora	Clinical App Specialist
Kim, Junkoo	Revenue Controller
King, Matthew L	VP of RA
Kirwin, Andrew	Human Factors Specialist
Lanier Jr, Gregory	VP of Engineering
Leblanc, Stephanie	Account Manager
Lee, Alan	Director Enterprise Apps
Lee, Changying F	Treasurer
Lee, Frederick	Chief Executive Officer
Leong, Emily	R&D Systems Engineering Intern
Li, Bosen	Sr Eng, Int & Testing Lead
Li, Han	Senior Software Engineer
Li, Jingran	Staff Eng, System Eng Lead
Li, Yancen	Staff Eng, Software Developer
Liang, Annie	Supplier Quality Manager
Liang, Zhongzheng	Engineer II - Int & Testing
Liao, Shunyou	Senior Staff Accountant
Liu, Zhuoran	Principal SQA Eng/Tech Lead
Luk, Daryl T	Director, Software Engineering
Ly, Nam T	Senior Software Engineer
Mao, Zhenhua	R&D Fellow
Maroney, James R	Manager Customer Service
Matos, Jesus M	Sr Complaint Handling Spec.
McCurdy, Tom	Chief Commercial Officer
Melnyk, Connor J	Associate Proj Mgr- Sustaining
Mirkazemi, Jamileh S	Accounts Payable I
Mitchell, Wade C	Mechanical Engineer I
Nguyen, Minh H	Senior Systems Engineer
Nikki, Peter	Quality Operations Manager
OKeefe, Kelly M	Quality Operations Specialist

Palianytsia, Olha	Purchasing Manager
Parker, George	Consultant
Parks, David Q	VP of IT Operations
Penado JR, Ricardo A	System Administrator
Piccione, Tina L	Regional Sales Manager
Pires, Leda F	Accountant
Poulsen, Vincent	Account Manager
Reading, Stephen M	Salesforce Administrator
Richard, Marisa	Human Resources Manager
Robinson, Maryann	Shipping & Receiving Lead
Romano, Bryan D	Sr Director, Ops & Supp. Chain
Serame, Chas	Clinical Educator
Shie, Wenmei	Senior SW QA Engineer
Smith, Michael	Director Product Management
Stanley, James	Regional Sales Manager
Stout, Michael J	R&D Fellow
Sun, Jingwen	Engineer II - Software Quality
Talbot, Janet L	Senior Program Manager
Templeton, Keith D	General Manager CE
Tian, Chongfang	Staff Eng, Software Developer
Tolbert, A Fedesco C	Senior System Administrator
Tom McCurdy	Chief Commercial Officer
Torchio, Michael T	Senior Software Engineer
Van, Jeffrey	Buyer
Wahl, Samantha T	Customer Service Coordinator
Wang, Chen	Senior Software Engineer
Wang, Johnny	Principal Eng, Software Dev
Wang, Xiaoying	Regulatory Affairs Specialist
Wang, Ximing	Software Engineer
Wood, Donna M	Accounting Assistant
Wood, Kent	Senior SW QA Engineer
Wu, Yujue	Cost Controller
Xiao, Jiachen	Engineer I - Software Quality
Xu, Shihao	Senior Software Engineer
Xu, Yidi	Sr Software Quality Engineer
Yan, James Zhimin	R&D Fellow
Yang, Jingmei	Director of SW Development
Ying, Binxian	Engineer II - Mechanical Eng
Yuan, Yuan	Sr Software Quality Engineer
Zeng, Gloria	Complaint Eval Specialist
Zhou, Yimai	Engineer II - Software Dev
Zhu, Anpu	Senior Systems Engineer
Zhu, Yi	Software Engineer
Zhuang, Yan	Senior SW QA Engineer
Zimmardi, Marie L	Customer Service Coordinator

Zuschlag, Caitlin M	QA Systems & Compliance Mgr
Zygouras, George V	Senior System Administrator

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: The Flume Catheter Company Inc.

Physical Address: 2825 E. Cottonwood Parkway , Suite 500, Office 524

City: Salt Lake City State: UT Zip: 84121

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: https://www.flumecatheter.com/

Name of Designated Representative (DR): Kristian Josef Olsen

Licensing Company Email: FCC@slsny.com DR Email: Kristian@flumecatheter.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer - Virtual
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Biomerics
Address: 6030 W Harold Gatty Dr City: Salt Lake City State: UT Zip: 84116

Name: Temecula Custom Extrusions Inc.
Address: 41984 Rio Nedo Rd STE 100 City: Temecula State: CA Zip: 92590

Name: SteriPax Inc.
Address: 5412 Research Dr City: Huntington Beach State: CA Zip: 92649

Name: Consolidated Label Co.
Address: 2001 E Lake Mary Blvd City: Sanford State: FL Zip: 32773

N/A **Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): The Flume Catheter Company Limited
Corporation/Organization Name: The Flume Catheter Company Inc.
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: FCC@slsny.com
Contact Person Name: Christine Cannon

N/A **Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A **Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Please see attached product list with UDI # needed for devices only	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019 Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

The Flume Catheter Company Inc.

Facility Name

James Edward Oury

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9 23 23

Date

Board Use Only	Date Received: 10/7/24	Amount: $1000-CK 401412

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
THE FLUME CATHETER COMPANY LTD
The Granary, Mill House
Frensham
Farnham Surrey, GB GU10 3EE
Registration Number: 3022516937
FEI Number*: 3022516937
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
The Flume Catheter Company Ltd[6]
The Granary, Mill House
Frensham
Farnham, Surrey GB GU10 3EE
Owner/Operator Number: 10084981[7]

Official Correspondent:
Kristian Olsen
The Flume Catheter Company Inc
2825 E. Cottonwood, Parkway Suite 500
Office 524
Salt Lake City, UT 84121
Phone: 801-8241399

US Agent:
Elaine Duncan
Paladin Medical Inc
415 Valley View Trail
Houlton, WI US 54082
Phone: 715 5496035 Ext
Email: Duncan@Paladinmedical.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 10/07/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/

Product List w/ UDI #

FLUME Catheter UDI Numbers for Product we will be shipping out of LSL

Item	Description	UDI #	Quantity
1006	FLUME catheter & Syringe Kit 375mm 16Fr US (Pillow Box)	(01)05060894850049(10)BSLC4684(17)250430	119
1006	FLUME catheter & Syringe Kit 375mm 16Fr US (Pillow Box)	(01)05060894850049(10)BSLC4685(17)250430	94

Item	Description	UDI #	Quantity
1004	FLUME catheter & Syringe Kit 375mm 14Fr US (Pillow Box)	(01)05060894850032(10)BSLC4686(17)250430	99

The Flume Catheter Company Inc.

Corporate Address: 2825 E. Cottonwood Parkway, Suite 500 Office 524, Salt Lake City, UT 84121 USA
FEIN: 88-2393159
https://www.flumecatheter.com/

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 05/17/2022

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
ECP	2825 E. Cottonwood Parkway Suite 500, Office 524 Salt Lake City, UT 84121 County: Salt Lake	N/A	N/A - No CS	112488546	No	(949) 464-4400	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Kristian Josef Olsen	2825 E. Cottonwood Parkway Suite 500 Salt Lake City, UT 84121	Designative Representative	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
The Flume Catheter Company Limited	The Granary Mill House, Mill Lane, Surrey County Frensham, Farnham, GU103EE United Kingdom	N/A	100	N/A	1152811884	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
James Edward Oury	[redacted]	Secretary	No	[redacted]		
Roger Anthony Holmes		President, Treasurer, CEO	No			
Doctor John Spencer Havard		Chairman of the Board, Founder, CMO				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Rocket Lawyer LLC			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
LifeScience Logistics, LLC	1105 E. Northfield Drive Brownsburg, IN 46112					

Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "THE FLUME CATHETER COMPANY INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTIETH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "THE FLUME CATHETER COMPANY INC." WAS INCORPORATED ON THE SEVENTEENTH DAY OF MAY, A.D. 2022.

Jeffrey W. Bullock, Secretary of State

6803019 8300

SR# 20240284873

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202703017

Date: 01-30-24

Verification of HS License

SPENCER J. COX
Governor
DEIDRE M. HENDERSON
Lieutenant Governor

State of Utah
Department of Commerce
Division of Professional Licensing

MARGARET W. BUSSE
Executive Director

MARK B. STEINAGEL
Division Director

VERIFICATION OF UTAH LICENSURE

Created On: 09/05/2024

This verification is considered a primary source from the State of Utah.

Name of Licensee (as it appears in our records): The Flume Catheter Company Inc

Classification of License Issued: Pharmacy - Class C

Specialties: Manufacturer, Virtual

License Number: 13843963-1710

Obtained By: Application

Current Status: Active

Original Date of Licensure: 03/05/2024

Expiration Date: 09/30/2025

Agency and Disciplinary Action: NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**

Docket and Citation Number(s):

E-Prescriber:

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. This verification form does not show a complete history or interruptions in licensure. If you have any questions please contact the division.

www.dopl.utah.gov • Heber M. Wells Building • 160 East 300 South • PO Box 146741 • Salt Lake City • UT 84114-6741
phone: (801)530-6628 • toll-free in Utah:(866)275-3675 • fax:(801)530-6511 • investigations fax:(801)530-6301

Home State Permit

Home State License

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

The Flume Catheter Company Inc

EFFECTIVE
03/05/2024

EXPIRATION
09/30/2025

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13843963-1710 Pharmacy - Class C

Manufacturer
Virtual

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

THE FLUME CATHETER COMPANY INC
2825 E COTTONWOOD PKWY STE 500 OFFICE 524
SALT LAKE CITY UT 84121

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **03/05/2024**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **The Flume Catheter Company Inc**
2825 E Cottonwood Pkwy Ste 500 Office 524
Salt Lake City UT 84121

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13843963-1710 **Pharmacy - Class C**

Manufacturer
Virtual

DBAs: **None Associated**

Form #1

5 December 2024

To whom it may concern,
RE: The Flume Catheter Company Ltd
Address: The Granary, Mill House, Frensham Farnham, Surrey, GU10 3EE
And its 100% owned subsidiary
The Flume Catheter Company Inc.
2140 South Dupont Parkway, Suite 500, Office 524, Salt Lake City, UT
84121 U.S.
Our Reference: 50846027

We can confirm that we act as insurance brokers on behalf of the above insured, and that the following covers are in place:

Business Activities/Description:

The purpose of The Flume Catheter Company is to develop and market an improved alternative to the long standing Foley indwelling urinary catheter.

Employers Liability

Insurer:	CFC Underwriting Ltd underwritten by Zurich Insurance Company Ltd
Policy Reference:	BSM0039818618
Cover Period:	11th November 2024 to 10th November 2025
Indemnity Limit:	$12,787,500 any one claim

Public Liability

Insurer:	CFC Underwriting Ltd underwritten by Zurich Insurance Company Ltd
Policy Reference:	BSM0039818618
Cover Period:	11th November 2024 to 10th November 2025
Indemnity Limit:	$2,557,500 any one claim
Excess:	$328

Products Liability

Insurer:	CFC Underwriting Ltd underwritten by Zurich Insurance Company Ltd
Policy Reference:	BSM0039818618
Cover Period:	11th November 2024 to 10th November 2025
Indemnity Limit:	$6,364,211 any one claim and any one period
Excess:	$12,728

Please Note:

This is at today's (12/11/2024) currency exchange rate and is subject to change.

The information provided in this document provides a brief overview of cover in place at the time this was sent. The full details of the above policy, including terms and conditions, are provided in their respective policy documentation. The expiry date given represents the normal expiry date of the policy. This document does not change cover provided. The cover stated above may change or be cancelled, and we are under no obligation to advise you as such.

Please contact us if you require any further information.

Yours faithfully,

Laura Sunley
DIP CII
Client Adviser
Partners&
T: 01865 953112
E: laura.sunley@partnersand.com

Bond

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101229747

Application/License No. _____

The Flume Catheter Company Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2825 E Cottonwood Pkwy, Suite 500, Office 524 Salt Lake City, UT 84121 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of August, 20 24.

APPLICANT/PRINCIPAL

The Flume Catheter Company Inc

Authorized Representative

ROGER HOLMES

SURETY COMPANY

Merchants Bonding Company (Mutual)
Surety Company's Representative

Jeremy Crawford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

ABATUNDE. O. OYEBODE
Witness

Hannah Lamski
Witness Hannah Lamski

CHRISTINA OYEBODE
Witness

Natalie Hildebrandt
Witness Natalie Hildebrandt

Countersigned by:

Nevada Resident Agent Jeremy Crawford

LP 4229 NV (5/21)

Posted February 20, 2020

MERCHANTS
BONDING COMPANY

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Jeremy Crawford

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and April 27, 2024 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015 and amended on April 27, 2024.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 2nd day of August , 2024 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 2nd day of August , 2024 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 2nd day of August , 2024 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

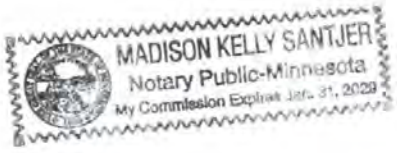
Secretary

POA 0018 (6/24)

Acknowledgment of Surety

State of Minnesota
County of Hennepin

On this 2nd day of August, 2024 before me personally appeared **Jeremy Crawford** who acknowledged that he or she is the attorney in fact who is authorized to sign on behalf of **Merchants Bonding Company** (surety company), the foregoing instrument, and he thereupon duly acknowledged to me that he executed the same.



Madison Santjer
Notary Public

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG The Flume Catheter Company Inc. MDEG License # (if applicable) N/A

Physical Address 2825 E. Cottonwood Parkway , Suite 500, Office 524

City Salt Lake City State UT Zip 84121

Mailing Address (if different from physical address) c/o State License Servicing c/o State License Servicing, 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website https://www.flumecatheter.com/

Licensing Company Email FCC@SLSNY.com

Section 2: Personal Information

First Kristian Middle Josef Last Olsen

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address c/o State License Servicing 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephon [redacted] Email Kristian@flumecatheter.com

Are you a citizen of the United States? ☒ Yes No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/1997 - 05/2007	
Address	City	State	Zip
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Alta High School		09/90 – 06/93	
Address	City	State	Zip
11055 S. 1000 E.	Sandy	UT	84094
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2022 - Present	[redacted]	Millcreek	UT	84124
05/2021 - 02/2022		Salt Lake City	UT	84124
01/2020 - 04/2021		Draper	UT	84020
05/2015 - 12/2019		Saratoga Springs	UT	84103
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
The Flume Catheter Company Inc.			11/2023 - Present	
Business Address		**City**	**State**	**Zip**
2825 E. Cottonwood Parkway, Suite 500		Salt Lake City	UT	84121
Phone	**Title**		**Number of Employed Hours**	
(801) 824-1399	Designative Representative		~ 1,720 hrs	

Description of Duties

Manage engineering and manufacturing of the Flume Urinary Catheter. Production transfer from Utah to a contract manufacturer in Guangzhou, China. Manage all activities at Salt Lake City division of The Flume Catheter Company. Design development of next-gen urinary catheters. Licensed Designated Representative - California State Board of Pharmacy.

Business Name			From - To (MM/YY – MM/YY)	
Natus Medical			05/2023 - 11/2023	
Business Address		**City**	**State**	**Zip**
5955 Pacific Center Blvd		San Diego	CA	92121
Phone	**Title**		**Number of Employed Hours**	
(925) 223-6700	Sr. Catheter Engineer		~ 1,200 hrs	

Description of Duties

Managed Intracranial Pressure Catheter development program as well as product support for cerebral spinal fluid drain.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Kristian Josef Olsen, **certify that as the MDEG Administrator for**

The Flume Catheter Company Inc.,

that I (initial that you have read and meet the following requirements):

1. KO Have a high school diploma or its equivalent;
2. KO Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KO Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KO Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristian Josef Olsen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/24
Date

Board Use Only	Date Received: 10/7/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: The Flume Catheter Company Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 2825 E. Cottonwood Parkway , Suite 500, Office 524

City: Salt Lake City State: UT Zip: 84121

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: https://www.flumecatheter.com/

Licensing Company Email: FCC@SLSNY.com

Section 2: Personal Information

First: Kristian Middle: Josef Last: Olsen

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Millcreek State: UT Zip: 84124

Telephone: (801) 824-1399 Email: Kristian@flumecatheter.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/1997 - 05/2007	
Address	**City**	**State**	**Zip**
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Alta High School		09/90 - 06/93	
Address	**City**	**State**	**Zip**
11055 S. 1000 E.	Sandy	UT	84094
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2022 - Present	[redacted]	Millcreek	UT	84124
05/2021 - 02/2022		Salt Lake City	UT	84124
01/2020 - 04/2021		Draper	UT	84020
05/2015 - 12/2019		Saratoga Springs	UT	84103
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
The Flume Catheter Company Inc.			11/2023 - Present	
Business Address		**City**	**State**	**Zip**
2825 E. Cottonwood Parkway , Suite 500, Office 524		Salt Lake City	UT	84121
Phone	**Title**		**Number of Employed Hours**	
(801) 824-1399	Designative Representative		~ 1,720 hrs	

Description of Duties
Manage engineering and manufacturing of the Flume Urinary Catheter. Production transfer from Utah to a contract manufacturer in Guangzhou, China. Manage all activities at Salt Lake City division of The Flume Catheter Company. Design development of next-gen urinary catheters. Licensed Designated Representative - California State Board of Pharmacy.

Business Name			From - To (MM/YY – MM/YY)	
Natus Medical			05/2023 - 11/2023	
Business Address		**City**	**State**	**Zip**
5955 Pacific Center Blvd		San Diego	CA	92121
Phone	**Title**		**Number of Employed Hours**	
(925) 223-6700	Sr. Catheter Engineer		~ 1,200 hrs	

Description of Duties
Managed Intracranial Pressure Catheter development program as well as product support for cerebral spinal fluid drain.

Business Name			From - To (MM/YY – MM/YY)	
Biomerics			12/2014 - 04/2023	
Business Address		**City**	**State**	**Zip**
6030 W Harold Gatty Dr		Salt Lake City	UT	84116
Phone	**Title**		**Number of Employed Hours**	
(801) 355-2705	Sr. Project Manager		~ 17,360 hrs	

Description of Duties
Managed medical device projects from idea through regulatory submission and market launch.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Kristian Josef Olsen, **certify that as the designated representative for**

The Flume Catheter Company Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KO I am at least 21 years of age;
3. KO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kristian Josef Olsen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/25/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristian Josef Olsen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/24

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Kristian Olsen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Kristian Josef Olsen

9/25/24

Date

Subscribed and Sworn to before me this 25th day of September.

Notary Public Signature

EMILY SNYDER
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 737136
COMM. EXP. 05/09/2028

(Seal)

Employee List

FLUME

List of Employees

Kristian Olsen

The Flume Catheter Company Inc
2825 E. Cottonwood Parkway
Suite 500, Office 524
Salt Lake City, UT 84121

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: 365 DME, LLC

Physical Address: 9860 Hudson Road

City: Pittsford State: MI Zip: 49271

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 517-997-5938 Website: https://www.365dme.com/

Name of Designated Representative (DR): Robyn Jones

Licensing Company Email: _____ DR Email: Credentialing@365mbs.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Robyn M Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Terrain RX

Address: 3650 Mayberry Dr. Suite # 102-2 City: Reno State: NV Zip: 89509

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name: Robyn Jones

Business Name: 365 DME

Business Address: 9860 Hudson Rd

City: Pittsford State: MI Zip: 49271

Telephone: 517-997-5938 Email: credentialing@365mbs.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓ NA
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** N/A	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

365 DME, LLC
Facility Name

Robyn Jones
Print Name of Authorized Person Submitting Application

Robyn M Jones
Original Signature of Authorized Person (copies or stamps not accepted)

8-28-24
Date

Board Use Only	Date Received: 9/24/24	Amount: $1000-ck 31657

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

365 DME LLC

was validly authorized on March 19 , 2021, as a Michigan
DOMESTIC LIMITED LIABILITY COMPANY
and said limited liability company is validly in existence under the laws of this state and has satisfied its annual filing obligations.

This certificate is issued pursuant to the provisions of 1993 PA 23 to attest to the fact that the company is in good standing in Michigan as of this date.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 26th day of April , 2024.

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

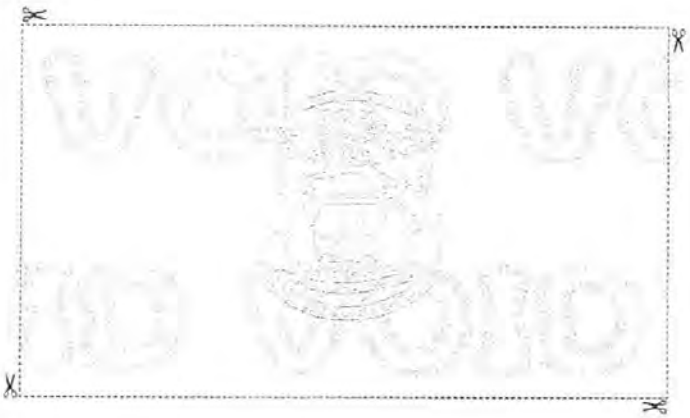
Sent by electronic transmission

Certificate Number: 24040599102

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

22TMP-0009PK



365 DME LLC
DBA - 365 DME
9860 HUDSON RD
PITTSFORD, MI 49271

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

Q782001

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

365 DME LLC
DBA - 365 DME
9860 HUDSON RD
PITTSFORD, MI 49271

LICENSE NO.
5306006880

EXPIRATION DATE
12/17/2025

23298041001

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

365DMEL-01 NCARLSON

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 8/7/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Nancy Carlson	
Acrisure Great Lakes Partners Insurance Services, LLC 223 West Grand River Ave #1 Howell, MI 48843	PHONE (A/C, No, Ext): (231) 932-0265	FAX (A/C, No):
	E-MAIL ADDRESS: ncarlson@acrisure.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Benchmark Insurance Company	41394
INSURED	INSURER B :	
365 DME, LLC 9860 Hudson Rd Pittsford, MI 49271	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	CLAIMS-MADE X OCCUR			D1023G65884	8/11/2024	8/11/2025	EACH OCCURRENCE	$ 1,000,000
	X Professional Liab						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

INSURANCE VERIFICATION PURPOSES

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TCS28115

Application/License No. _____

365 DME, LLC, doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

9860 Hudson Rd, Pittsford, MI 49271, as
Address of Applicant/Principal
PRINCIPAL, and Hudson Insurance Company, a
Surety Company
corporation organized under the laws of the state of Delaware
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address

for purposes of service is

8777 N Gainey Center Dr Ste 240, Scottsdale, AZ 85258-2154 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 09/10/2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10th day of September, 20 24.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Joshua Kayser, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Jolene Pickford

Witness

JOLENE PICKFORD
Notary Public, State of Michigan
County of Hillsdale
My Commission Expires 10-05-2030
Acting in the County of Hillsdale

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A Retaliatory

Nevada Resident Agent

TCS28115

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Joshua Kayser

of the State of Missouri

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars and Zero Cents

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly d, on this 2nd day of June, 20 22 at New York, New York.

: seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY NOTARY PUBLIC STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 10th day of September, 20 24.

seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG 365 DME, LLC MDEG License # (if applicable) _____

Physical Address 9860 Hudson Rd

City Pittsford State MI Zip 49271

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 517-997-5938 Website www.365DME.com

Licensing Company Email _____

Section 2: Personal Information

First Robyn Middle Michelle Last Jones

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City OSSeO State MI Zip 49266

Telephone 517-997-5938 Email Credentialing@365mhs.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwood High School		1992 - 1996	
Address	City	State	Zip
6000 Lemoyne Road	North Wood	OH	43619
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Current	[redacted]	Osseo	MI	49266
2012 - 2020		Osseo	MI	49266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
365 Medical Billing Services			2013 - Current	
Business Address		City	State	Zip
115 S. Church St.		Hudson	MI	49247
Phone	Title		Number of Employed Hours	
517-306-6189	Owner		1,500 +	
Description of Duties				
Run the Company				

Business Name			From - To (MM/YY – MM/YY)	
365 DME			2019 - Current	
Business Address		City	State	Zip
4860 Hudson Rd		Pittsford	MI	49271
Phone	Title		Number of Employed Hours	
517-997-5938	Owner		1,500 +	
Description of Duties				
Run the Company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Robyn M Lovell
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

I, Robyn Jones, **certify that as the MDEG Administrator for**

365 DME, LLC,

that I (initial that you have read and meet the following requirements):

1. RJ Have a high school diploma or its equivalent;
2. RJ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RJ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RJ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones
Print Name (First, Last)

Robyn M Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Board Use Only	Date Received: 9/24/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler 365 DME, LLC

Pharmacy/Wholesaler License # (if applicable) Michigan Wholesaler 53[illegible]6830

Physical Address 9560 Hudson Rd

City Pittsford State MI Zip 49271

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 517-997-5938 Website www.365dme.com

Licensing Company Email Credentialing@365mbs.com

Section 2: Personal Information

First Robyn Middle Michelle Last Jones

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Ossco State MI Zip 49266

Telephone 517-997-5938 Email Credentialing@365mbs.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwood Highschool		1992 - 1996	
Address	City	State	Zip
600 Lemoyne Road	Northwood	OH	43619
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Current	[redacted]	Osseo	MI	49266
From - To (MM/YY – MM/YY)		City	State	Zip
2012 - 2020		Osseo	MI	49266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
365 DME			2019-Current	
Business Address		**City**	**State**	**Zip**
9860 Hudson Rd		Pittsford	MI	49271
Phone	**Title**		**Number of Employed Hours**	
517-997-5938	Owner		6,000 +	
Description of Duties				
Run the Company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Robyn M Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

I, Robyn Jones, **certify that as the designated representative for**

365 DME, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RJ I am at least 21 years of age;
3. RJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robyn Jones
Print Name (First, Last)

Robyn Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones
Print Name (First, Last)

Robyn M Jones
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Lenawee

I, Robyn Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robyn M Jones
Original Signature

9/4/24
Date

Subscribed and Sworn to before me this 4th day of September.

Notary Public Signature

JOLENE PICKFORD
Notary Public, State of Michigan
County of Hillsdale
My Commission Expires 10-05-2030
Acting in the County of Hillsdale

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: 365 DME, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MI Wholesalers License:5306006880

Physical Address: 9860 Hudson Rd

City: Pittsford State: MI Zip: 49271

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 517-997-5938 Website: www.365dme.com

Licensing Company Email: Credentialing@365mbs.com

Section 2: Personal Information

First: Robyn Middle: Michelle Last: Jones

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Addres: [redacted]

City: Osseo State: MI Zip: 49266

Telephone: 517-997-5938 Email: credentialing@365mbs.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwood High School		1992-1996	
Address	City	State	Zip
600 Lemoyne Road	Northwood	OH	43619
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-current	[redacted]	Osseo	MI	49266
From - To (MM/YY – MM/YY)		City	State	Zip
2012-2020		Osseo	MI	49266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
365 Medical Billing Services			2013-2024 (current)
Business Address	**City**	**State**	**Zip**
115 S Church St	Hudson	MI	49247
Phone	**Title**		
517-306-6189	OWNER		
Description of Duties			
Run the company			

Business Name			From - To (MM/YY – MM/YY)
365 DME			2019-2024 (current)
Business Address	**City**	**State**	**Zip**
9860 Hudson Rd	Pittsford	MI	49271
Phone	**Title**		
517-997-5938	Owner		
Description of Duties			
Run the company			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robyn Jones

Print Name (First, Last)

Robyn M Jones

Original Signature (electronic, copies or stamps not accepted)

4/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Lenawee

I, Robyn Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robyn M Jones

Original Signature

9/4/2024

Date

Subscribed and Sworn to before me this 4 day of September.

Notary Public Signature

JOLENE PICKFORD
Notary Public, State of Michigan
County of Hillsdale
My Commission Expires 10-05-2030
Acting in the County of Hillsdale

(Seal)

List of Current Employees/Titles

Robyn Jones -Owner/ CEO

Joshua Barnett-Intake Representative

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Advanced Medical Sales, Inc.

Physical Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Mailing Address (if different from physical address): *Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 949-348-7912 Website: ams-rx.com

Name of Designated Representative (DR): Michael Rocha

Licensing Company Email: [redacted] DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	N/A

Reason/Charge
N/A

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

6/11/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson Corp
Address: 16043 El Prado Avenue City: Chino State: CA Zip: 91708

Name: Masters Drug Company, Inc.
Address: 3600 Pharma Way City: Mason State: OH Zip: 45036

Name: Fresenius Kabi USA, LLC
Address: 5245 N. Solan Lane, Suite 100A City: North Las Vegas State: NV Zip: 89115

Name: Cardinal Health
Address: 27680 Avenue Mentry City: Valencia State: CA Zip: 91355

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California
Parent Company (if any): N/A
Corporation/Organization Name: Advanced Medical Sales, Inc.
Mailing Address: 232 Avenida Fabricante, Suite 103/104
City: San Clemente State: CA Zip: 92672
Telephone: 949-348-7912 Email: [redacted]
Contact Person Name: Michael Rocha

Section 6: Partnership

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Section 7: Sole Owner

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** ✓	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** ✓		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. ✓	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** ✓	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** ✓	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ ✓	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. ✓		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. ✓		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Advanced Medical Sales, Inc.

Facility Name

Michael Rocha

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/11/2024

Date

Board Use Only	Date Received: 8/16/24	Amount: $1000-ck 2909

Ownership & Corporate Structure

Advanced Medical Sales, Inc.

Owner:

- The Michael James Rocha and Shannon Janelle Rocha Family Trust DTD 12/03/14
  - 9 Broken Arrow St., Ladera Ranch, CA 92694
  - Ownership Percentage: 100%
  - TIN: 560-57-7356

❖ Trustees:

- Michael Rocha
  - [redacted]
  - Business: 232 Avenida Fabricante #103/104, San Clemente, CA 92672
  - Contact Phone: 949-348-7912
  - [redacted]
  - [redacted]
- Shannon Rocha
  - [redacted]
  - Business: 232 Avenida Fabricante #103/104, San Clemente, CA 92672
  - Contact Phone: 949-348-7912
  - [redacted]
  - [redacted]

Executive Officers:

- Michael Rocha
  - CEO / CFO / Secretary / Treasurer
  - President / Vice President

Directors:

- Michael Rocha
- Shannon Rocha

Designated Representatives:

- Advanced Medical Sales, Inc.
  - 232 Avenida Fabricante #103/104, San Clemente, CA 92672
    - Michael Rocha

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	ADVANCED MEDICAL SALES, INC.
Entity No.:	1718049
Registration Date:	01/07/1993
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 15, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 191597531

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8378

ISSUE DATE DECEMBER 08, 2023

ADVANCED MEDICAL SALES INC
232 AVENIDA FABRICANTE STE 103/104
SAN CLEMENTE CA 92672

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
MICHAEL J. ROCHA — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL DECEMBER 01, 2024

RECEIPT NUMBER 00755983

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

2/08/24
2/08/24

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

BOARD OF PHARMACY

ISSUANCE DATE
DECEMBER 8, 2023
EXPIRATION DATE
DECEMBER 1, 2024
CURRENT DATE / TIME
MAY 3, 2024
3:0:36 PM

LICENSING DETAILS FOR: WLS 8378

NAME: ADVANCED MEDICAL SALES INC
LICENSE TYPE: WHOLESALER
LICENSE STATUS: CLEAR

ADDRESS
232 AVENIDA FABRICANTE STE 103/104
SAN CLEMENTE CA 92672
ORANGE COUNTY

LICENSE RELATIONSHIPS

NAME: ROCHA, MICHAEL J
LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)
LICENSE NUMBER: 17553 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Phone: (714) 973-1436 Fax: (714) 973-0811
ELMCO INSURANCE, INC.
636 E CHAPMAN AVENUE
ORANGE CA 92866
Agency Lic#: 0509747

CONTACT NAME: ELMCO INSURANCE, INC.
PHONE (A/C, No, Ext): (714) 973-1436 FAX (A/C, No): (714) 973-0811
E-MAIL ADDRESS: contact@Elmcoinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : LIBERTY SURPLUS INSURANCE CORPORATION	
INSURER B : MESA UNDERWRITERS SPECIALTY INSURANCE COMPANY	
INSURER C :	
INSURER D:	
INSURER E :	
INSURER F :	

INSURED
ADVANCED MEDICAL SALES, INC
2304 SEABORNE ROAD, #100
PONDER, TX 76259

COVERAGES **CERTIFICATE NUMBER:** 77580 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			APU000258-06	05/01/24	05/01/25	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED. EXP (Any one person)	$
							PERSONAL & ADV INJURY	$ INCLUDED
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ INCLUDED
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N						E.L. EACH ACCIDENT	$
	(Mandatory in NH) N/A						E.L. DISEASE-EA EMPLOYEE	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE SUPPLEMENTAL CERTIFICATE INFORMATION

CERTIFICATE HOLDER

Nevada State Board of Pharmacy

Attention:

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Veronica Acosta

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SUPPLEMENT TO CERTIFICATE OF LIABILITY INS # 77580

DATE
SEP 22 2024

DESCRIPTION OF OPERATIONS, LOCATIONS, VEHICLES

2304 Seaborn Road, #100
Ponder, TX 76259

232 Avenida Frabricante Ste 103/104
San Clemente, CA 92672

Certificate # 77580

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 72644B68

Application/License No. _____

Advanced Medical Sales, Inc. (Applicant /Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is

Ste. 103-104 232 Avenida Fabricante, San Clemente, CA 92672 (Address of Applicant /Principal), as PRINCIPAL, and WESTERN SURETY COMPANY (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

P. O. Box 5077, Sioux Falls, SD 57117-5077 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 14th, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

Western Surety Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That WESTERN SURETY COMPANY, a corporation organized and existing under the laws of the State of South Dakota, and authorized and licensed to do business in the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the United States of America, does hereby make, constitute and appoint

Larry Kasten of Sioux Falls,

State of South Dakota, *its regularly elected* Vice President,

as Attorney-in-Fact, with full power and authority hereby conferred upon him to sign, execute, acknowledge and deliver for and on its behalf as Surety and as its act and deed, the following bond:

One Prescription Drug Wholesale Distributor

bond with bond number 72644868

for Advanced Medical Sales, Inc.

as Principal in the penalty amount not to exceed: $100,000.00

Western Surety Company further certifies that the following is a true and exact copy of Section 7 of the by-laws of Western Surety Company duly adopted and now in force, to-wit:

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys-in-Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

In Witness Whereof, the said WESTERN SURETY COMPANY has caused these presents to be executed by its Vice President with the corporate seal affixed this 29th day of May, 2024.

ATTEST

L. Bauder, Assistant Secretary

WESTERN SURETY COMPANY

By

Larry Kasten, Vice President

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

STATE OF SOUTH DAKOTA }
COUNTY OF MINNEHAHA } ss

On this 29th day of May, 2024, before me, a Notary Public, personally appeared Larry Kasten and L. Bauder who, being by me duly sworn, acknowledged that they signed the above Power of Attorney as Vice President and Assistant Secretary, respectively, of the said WESTERN SURETY COMPANY, and acknowledged said instrument to be the voluntary act and deed of said Corporation.

M. BENT NOTARY PUBLIC SOUTH DAKOTA SEAL SEAL

M. Bent

Notary Public

My Commission Expires March 2, 2026

To validate bond authenticity, go to www.cnasurety.com > Owner/Obligee Services > Validate Bond Coverage.

Form F1975-11-2022

Western Surety Company

RIDER

To be attached to and form part of Bond No. 72644868

It is hereby mutually agreed and understood by and between Western Surety Company and **Advanced Medical Sales, Inc.**

that instead of as originally written; the bond is changed or revised in the particulars checked below:

- ☐ **Principal Name changed to:**
- ☐ **Principal Address changed to:**
- ☐ **Vehicle/Vessel/Hull Information changed to:**
- ☐ **Lost Instrument Information changed to:**
- ☐ **Identification Number changed to:**
- ☐ **Penalty Amount changed to:**
- ☒ **Additional or Event Location: Addition Location:**
  Advanced Medical Sales, Inc., 2304 Seaborn Rd, Ste 100, Ponder, TX 76259
- ☐ **Effective Date changed to:**
- ☐ **Expiration Date changed to:**
- ☐ **The following bond information changed:**

But in no event shall Western Surety Company's total liability for all locations exceed the aggregate amount set forth in the bond, regardless of the number of years this bond remains in force, the number of claims made, or the number of renewal premiums payable or paid.
It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider becomes effective on the 14th day of May, 2024.

Signed this 29th day of May, 2024.

WESTERN SURETY COMPANY

By: _____
Larry Kasten, Vice President

Form F9586

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Advanced Medical Sales, Inc. MDEG License # (if applicable) _____

Physical Address 232 Avenida Fabricante, Suite 103/104

City San Clemente State CA Zip 92672

Mailing Address (if different from physical address) ** Same as Physical Address

City _____ State _____ Zip _____

Telephone 949-348-7912 Website ams-rx.com

Licensing Company Email Compliance@ams-rx.com

Section 2: Personal Information

First Michael Middle James Last Rocha

Alias(es, nicknames, name changes, etc.) [redacted]

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 232 Avenida Fabricante, Suite 103/104

City San Clemente State CA Zip 92672

Telephone 949-348-7912 Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 05/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences emphasis Economics			

School Name		From - To (MM/YY – MM/YY)	
Santa Margarita Catholic High School		09/94 - 06/98	
Address	**City**	**State**	**Zip**
22062 Antonio Pkwy	Rancho Santa Margarita	CA	92688
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Current	[redacted]	[redacted]	CA	92694
06/18 - 03/23			CA	92677
02/10 - 06/18			CA	92673
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			03/03 - Current	
Business Address		**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104		San Clemente	CA	92672
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	President / CEO		40,000	
Description of Duties				
Responsible for general management of all aspects of business operations for a national pharmaceutical distributor.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

06/11/2024
Date

I, Michael Rocha, **certify that as the MDEG Administrator for**

Advanced Medical Sales, Inc.,

that I (initial that you have read and meet the following requirements):

1. MR Have a high school diploma or its equivalent;
2. MR Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Rocha
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

Board Use Only	Date Received: 8/6/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Advanced Medical Sales, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Mailing Address (if different from physical address): *Same as Physical Address

City: -- State: -- Zip: --

Telephone: 949-348-7912 Website: ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Michael Middle: James Last: Rocha

Alias(es, nicknames, name changes, etc.): [redacted]

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 05/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences emphasis Economics			

School Name		From - To (MM/YY – MM/YY)	
Santa Margarita Catholic High School		09/94 - 06-98	
Address	**City**	**State**	**Zip**
22062 Antonio Pkwy	Rancho Santa Margarita	CA	92688
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Present	9 Broken Arrow St.	Ladera Ranch	CA	92694
06/18 - 03/23	36 Newcastle Lane	Laguna Niguel	CA	92677
02/10 - 06/18	4430 Mar Escarpa	San Clemente	CA	92673
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			03/03 - Current	
Business Address		**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104		San Clemente	CA	92672
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	President / CEO		~ 42,000 Hours	
Description of Duties				
Responsible for general management of all aspects of business operations for a national pharmaceutical distributor.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

I, Michael James Rocha, **certify that as the designated representative for**

Advanced Medical Sales, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MR I am at least 21 years of age;
3. MR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/4/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/11/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Michael Rocha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/4/2024

Date

Subscribed and Sworn to before me this 11th day of June 2024

Notary Public Signature

RYAN PATRICK MOREAU
Notary Public - California
Orange County
Commission # 2402485
My Comm. Expires Apr 28, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advanced Medical Sales, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Mailing Address (if different from physical address): ** Same as Physical Address

City: -- State: -- Zip: --

Telephone: 949-348-7912 Website: Ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Michael Middle: James Last: Rocha

Alias(es, nicknames, name changes, etc.): [redacted]

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 05/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences emphasis Economics			

School Name		From - To (MM/YY – MM/YY)	
Santa Margarita Catholic High School		09/94 - 06/98	
Address	**City**	**State**	**Zip**
22062 Antonio Pkwy	Rancho Santa Margarita	CA	92688
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Current	[redacted]	[redacted]	CA	92694
06/18 - 03/23			CA	92677
02/10 - 06/18			CA	92673
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			03/03 - Current	
Business Address		**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104		San Clemente	CA	92672
Phone	**Title**			
949-348-7912	President / CEO			
Description of Duties				
Responsible for general management of all aspects of business operations for a national pharmaceutical distributor.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/11/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Michael Rocha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/11/24

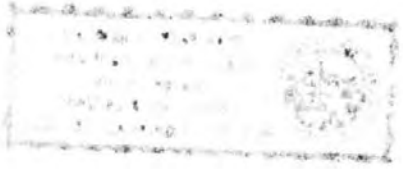
Date

Subscribed and Sworn to before me this 11th day of June.

Notary Public Signature

RYAN PATRICK MOREAU
Notary Public - California
Orange County
Commission # 2402485
My Comm. Expires Apr 28, 2026

(Seal)



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advanced Medical Sales, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Mailing Address (if different from physical address): ** Same as Physical Address

City: -- State: -- Zip: --

Telephone: 949-348-7912 Website: Ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Shannon Middle: Janelle Last: Rocha

Alias(es, nicknames, name changes, etc.): [redacted]

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 06/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences			

School Name		From - To (MM/YY – MM/YY)	
Huntington Beach High School		09/94 - 06/98	
Address	**City**	**State**	**Zip**
1905 Main St.	Huntington Beach	CA	92648
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Current	[redacted]	[redacted]	CA	92694
06/18 - 03/23			CA	92677
02/10 - 06/18			CA	92673
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			06/14 - Current	
Business Address		**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104		San Clemente	CA	92672
Phone	**Title**			
949-348-7912	Director			
Description of Duties				
Annual corporate meetings and general consultation.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title			
N/A	N/A			
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6-1-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shannon Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-1-24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Shannon Rocha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-1-24

Date

Subscribed and Sworn to before me this 1st day of June.

Notary Public Signature

RYAN PATRICK MOREAU
Notary Public - California
Orange County
Commission # 2402485
My Comm. Expires Apr 28, 2026

(Seal)

Employee Roster

Advanced Medical Sales, Inc.

Dba Advanced Med Sales, Inc.

❖ Location: 232 Avenida Fabricante, Suite 103/104, San Clemente, CA 92672

- **Executive Management / Designated Representative**
  - Michael Rocha

- **Sales Department**
  - Joshua Baisley
  - Cole Vietor
  - Mason Paine
  - Brianne Yepiz
  - Conor Good
  - Michele Rudin
  - Laurinho Walch

- **Acquisitions Department**
  - Jay Warren
  - Sarah Lattouf
  - Samantha Westgate
  - Alena Duffill

- **Administration**
  - Stephanie Rondini
  - Ryan Moreau
  - Nichole Anders
  - Christian Felix

- **Warehouse**
  - Stephen Radigan
  - Javier Hernandez
  - Robert Chapa

❖ Location: 2304 Seaborn Road #100, Ponder, TX, 76259

- **Management / Designated Representative**
  - Dezmon Gonzalez

- **Warehouse**
  - Gabriel Gonzales

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Drive DeVilbiss Healthcare

Physical Address: 500 Palmetto Logistics Parkway

City: Palmetto State: GA Zip: 30268

Mailing Address (if different from physical address): 99 Seaview Blvd

City: Port Washington State: NY Zip: 11050

Telephone: 516-998-4600 Website: www.drivemedical.com

Name of Designated Representative (DR): ~~Dionne Alford~~ William Waller

Licensing Company Email: licensing@drivemedical.com DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ ³Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: DME	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: State Medical
Address: 3950 E. Sunset road #112 City: Las Vegas State: NV Zip: 89120
Name: Professional Medical
Address: 5450 Mill Street #101 City: Reno State: NV Zip: 89502
Name: Vegas Medical Supplies
Address: 3111 S. Valley View blvd #A-105 City: Las Vegas State: NV Zip: 89102
Name: Sierra Healthcare
Address: 6720 Placid street City: Las Vegas State: NV Zip: 89119

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Medical Depot Holdings, Inc
Corporation/Organization Name: Medical Depot Inc. DBA Drive DeVilbiss Healthcare
Mailing Address: 99 Seaview Blvd.
City: Port Washington State: NY Zip: 11050
Telephone: 5169984600 Email: licensing@drivemedical.com
Contact Person Name: Zita Yurko

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Drive DeVilbiss Healthcare - Palmetto DC

Facility Name

William Waller

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/20/24

Date

Board Use Only	Date Received: 7/9/24	Amount: CC ✓

DeVilbiss HEALTHCARE
100 DeVilbiss Drive
Somerset, PA 15501 USA
800.338.1988 • 814.443.4881
www.DeVilbissHealthcare.com

Director:
Derek Lampert

Officers:
Chief Executive Officer & President – Derek Lampert
Secretary – Nora Coleman

drive
DeVilbiss HEALTHCARE

Corporate Office
99 Seaview Blvd., Port Washington, NY 11050
Toll Free: 877.224.0946 • 516.998.4600
www.drivemedical.com

Ownership Information

(1) full legal name
Medical Depot Holdings, Inc.

(2) Federal Employer Identification Number
11-3525013

(3) mailing address
99 Seaview Blvd., Ste 210
Port Washington, NY 11050

(4) telephone number
516-998-4600

(5) percentage of ownership or fraction thereof, and (6) an accounting for 100% of the ownership of the organization

100%

Corporate Office
99 Seaview Blvd., Port Washington, NY 11050
Toll Free: 877.224.0946 • 516.998.4600
www.drivemedical.com

Ownership

Medical Depot Holdings, Inc.,

99 Seaview Blvd
Port Washington, NY 11050
Nassau County

Phone: 516-998-4600

FEIN: 46-3740994

100% owner

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MEDICAL DEPOT, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MEDICAL DEPOT, INC." WAS INCORPORATED ON THE TWELFTH DAY OF JANUARY, A.D. 2000.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3154830 8300

SR# 20241267345

Authentication: 203160782

Date: 04-02-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0751151

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

99 SEAVIEW BLVD PORT WASHINGTON, NY 11050-
500 PALMETTO LOGISTICS PKWY ATLANTA,GA 30349-
200 DOCKS CORNER RD SOUTH BRUNSWICK, NJ 08852-

Reg. No.
5004723

MEDICAL DEPOT INC
DRIVE DEVILBISS HEALTHCARE
99 SEAVIEW BLVD STE 210
PORT WASHINGTON, NY 11050-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0751139

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

100 DEVILBISS DR SOMERSET, PA 15501-
401 LEONARD BLVD N LEHIGH ACRES,FL 33971-

Reg. No.
5005714

MEDICAL DEPOT, INC.
DRIVE DEVILBISS HEALTHCARE
99 SEAVIEW BLVD, STE 210
PORT WASHINGTON, NY 11050-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/19/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
30 Century Hill Drive
Suite 200
Latham NY 12110

CONTACT NAME: Christine M Zinoman, CPCU, AIC
PHONE (A/C, No, Ext): 518-724-6734 **FAX (A/C, No):** 518-869-3580
E-MAIL ADDRESS: Chris_Zinoman@ajg.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Great Northern Insurance Company	20303
INSURER C : Chubb Custom Insurance	38989
INSURER D : Great American Assurance Company	26344
INSURER E : Crum & Forster Specialty Insurance Co	44520
INSURER F : Travelers Indemnity Co of America	25666

INSURED
Medical Depot, Inc dba
Drive DeVilbiss Healthcare
99 Seaview Blvd.
Port Washington NY 11050

COVERAGES **CERTIFICATE NUMBER:** 1483350240 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			36032032	9/15/2023	9/15/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ **SEE BELOW**
B	AUTOMOBILE LIABILITY X ANY AUTO X OWNED AUTOS ONLY X SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			73599666	9/15/2023	9/15/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A E	X UMBRELLA LIAB X OCCUR X EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000 (U)			78186106 SEO126055	9/15/2023 9/15/2023	9/15/2024 9/15/2024	EACH OCCURRENCE AGGREGATE	$ *25,000,000 $ *25,000,000 $ *SEE BELOW
F F	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		UB9K7419582351K UB9K2932542351R	10/6/2023 10/6/2023	10/6/2024 10/6/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C D	PRODUCTS LIAB EXCESS LIAB EXCESS LIAB			36059025 EXC5126067	9/15/2023 9/15/2023	9/15/2024 9/15/2024	$10 Mil Ea Event/Agg $10 Mil x $25 Mil $15 Mil x $35 Mil	**SEE BELOW

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Insured - Blanket per Written Contract or Agreement Form 80-02-2367 (Rev 5-07)
Insured - Vendors - Liability Insurance Form 80-02-2085 (Ed 11-09)
Insured - Lessors of Premises Liability Insurance Form 80-02-2002 (Rev 4-01)
INSURER CODE E = Westfield Specialty Ins. Co, NAIC 24112, Policy # XSL00017HP01 + Crum & Forster Specialty Insurance Co Policy # SEO126055
INSURER CODE F = Travelers Indemnity Company of America and Travelers Property Casualty Co of America
*Total $25 Mil = $10 Mil Federal/Chubb Plus Quota Share Total of $15 Mil x $10 Mil [Each carrier $7.5 Mil part of $15 Mil Excess Liability]
**Excess Liability $15 Mil x $35 Mil with Endurance American Specialty Insurance Company Policy No ELD30001977103 eff 9/15/23 - 9/15/24
****NAMED INSURED****: Medical Depot, Inc dba Drive DeVilbiss Healthcare and its affiliates re:
See Attached...

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY Arthur J. Gallagher Risk Management Services, LLC	NAMED INSURED Medical Depot, Inc dba Drive DeVilbiss Healthcare 99 Seaview Blvd. Port Washington NY 11050
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: CERTIFICATE OF LIABILITY INSURANCE

Drive DeVilbiss Healthcare, Palmetto, GA
Drive DeVilbiss Healthcare, South Brunswick, NJ
Inovo Inc., Lehigh Acres, FL
DeVilbiss Healthcare LLC, Somerset, PA

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Gallagher
Insurance | Risk Management | Consulting

30 Century Hill Drive, Suite 200
Latham, NY 12110
United States

M - 518.869.3535
F - 518.869.3580
T - 888.869.3535
ajg.com

July 16, 2024

Ms. Judy Yeung
Drive DeVilbiss Healthcare
99 Seaview Blvd., Suite 210
Port Washington, NY 11050

Re: Bond No.: 30212202
Obligee: Nevada State Board of Pharmacy
Pharmaceutical Wholesaler Surety Bond
for Medical Depot Holdings, Inc. (South Brunswick, NJ)
Bond Amount: $100,000.00

Dear Judy,

Enclosed please find the above captioned ***REVISED*** Pharmaceutical Wholesaler Surety Bond which we ask that you have a corporate officer sign where indicated, have (2) witnesses sign where noted and have the notarial acknowledgment completed where shown.

Upon execution, please file the bond with the proper authorities. Thank you.

Very truly yours,

Jaymie Patricia Columbus
Client Service Supervisor
Surety Department

JPC/kar
Enclosures

Sent via UPS (07/16/2024)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30212201

Application/License No. [redacted]

Medical Depot Holdings, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 500 Palmetto Logistics Parkway, Palmetto, GA 30268 (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is c/o CNA Surety, 151 N. Franklin St., Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 21st, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of July, 2024.

APPLICANT/PRINCIPAL

Medical Depot Holdings, Inc.

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Jaymie Patricia Columbus, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kimberly A. Ritchie

Witness Kayley Klinkel

Countersigned by:

N/A
Nevada Resident Agent

INDIVIDUAL

STATE OF _____ }
COUNTY OF _____ } ss

On this _____ day of _____, _____, before me personally appeared _____ to me known and known to me to be the individual in and who executed the foregoing instrument and _____ acknowledged to me that _____ executed the same in his individual capacity.

_____
Notary Public

COPARTNERSHIP

STATE OF _____ }
COUNTY OF _____ } ss

On this _____ day of _____, _____, before me personally appeared _____ to me known and known to me to be one of the firm of _____ described in and who executed the foregoing instrument and he/she thereupon acknowledged to me that he/she executed the same as and for the act and deed of said firm.

_____
Notary Public

CORPORATE

STATE OF New York }
COUNTY OF Nassau } ss

On this 16 day of July, 2024, before me personally appeared Nora Coleman to me known, who, being by me first duly sworn, did depose and say that he/she resides in Port Washington, NY; that he/she is the EVP, General Counsel + Secretary of Medical Depot Holding's Inc. the corporation described in and which executed the foregoing instrument; that he/she knows the corporate seal of said corporation; that the corporate seal affixed to said instrument is such corporate seal; that it was so affixed by order and authority of the Board of Directors of said corporation, and that he/she signed his/her name thereto by like order and authority.

BARBARA J MAROLDA
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01MA6406056
Qualified in SUFF County
Commission Expires 03/23/2028

Barbara J Marolda
Notary Public

SURETY

STATE OF NEW YORK }
COUNTY OF ALBANY } ss

I, Kimberly A. Ritchie Notary Public of Rensselaer County, in the State of New York do hereby certify that Jaymie Patricia Columbus Attorney-in-Fact, of the Western Surety Company, who is personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me this day in person, and acknowledged that he/she signed, sealed and delivered said instrument, for and on behalf of the Western Surety Company, for the uses and purposes therein set forth.

Given under my hand and notarial seal at my office in the City of Latham in said County, this 16th day of July, A.D. 2024.

KIMBERLY A. RITCHIE
Notary Public, State of New York
No. 01RI6215612
Qualified in Rensselaer County
Commission Expires January 4, 2026

Kimberly A. Ritchie
Notary Public

Form F5345

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2023

ASSETS

Bonds	$	1,935,600,431
Stocks		15,281,696
Cash, cash equivalents, and short-term investments		36,335,353
Receivables for securities		14,770,000
Investment income due and accrued		18,185,645
Premiums and considerations		70,728,009
Amounts recoverable from reinsurers		4,459,042
Net deferred tax asset		18,202,272
Receivable from parent, subsidiaries, and affiliates		12,895,815
Other assets		157,742
Total Assets	$	2,126,616,005

LIABILITIES AND SURPLUS

Losses	$	247,328,673
Loss adjustment expense		56,340,495
Commissions payable, contingent commissions and other similar charges		13,245,319
Taxes, License and fees (excluding federal and foreign income taxes)		5,075,390
Federal and foreign income taxes payable		829,556
Unearned premiums		316,760,881
Advance premiums		6,183,112
Ceded reinsurance premiums payable (net of ceding commissions)		4,347,066
Amounts withheld or retained by company for account of others		3,094,680
Provision for reinsurance		157,388
Payable to parent, subsidiaries and affiliates		9,464
Other liabilities		(6,171)
Total Liabilities	$	653,365,853

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,182,353,957		
Surplus as regards policyholders		$	1,473,250,152
Total Liabilities and Capital		$	2,126,616,005

I, Julie Lee, Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2023, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Vice President, Accounting Policy & External Reporting

Subscribed and sworn to me this 14th day of March, 2024.

My commission expires:

YOLANDA JIMENEZ
OFFICIAL SEAL
Notary Public - State Of Illinois
My Commission Expires
September 24, 2025

By Yolanda Jimenez
Notary Public

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Michael Grasso, Charles C Leach, Jaymie Patricia Columbus, Kimberly Ritchie, Tiffany Gocha, Individually

of Latham, NY, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the Authorizing By-Laws and Resolutions printed at the bottom of this page, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 14th day of December, 2023.

WESTERN SURETY COMPANY

Larry Kasten, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 14th day of December, 2023, before me personally came Larry Kasten, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is a Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT NOTARY PUBLIC SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law and Resolutions of the corporation printed below this certificate are still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 16th day of July, 2024.

WESTERN SURETY COMPANY

L. Nelson, Assistant Secretary

Authorizing By-Laws and Resolutions

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

This Power of Attorney is signed by Larry Kasten, Vice President, who has been authorized pursuant to the above Bylaw to execute power of attorneys on behalf of Western Surety Company.

This Power of Attorney may be signed by digital signature and sealed by a digital or otherwise electronic-formatted corporate seal under and by the authority of the following Resolution adopted by the Board of Directors of the Company by unanimous written consent dated the 27th day of April, 2022:

"RESOLVED: That it is in the best interest of the Company to periodically ratify and confirm any corporate documents signed by digital signatures and to ratify and confirm the use of a digital or otherwise electronic-formatted corporate seal, each to be considered the act and deed of the Company."

Go to www.cnasurety.com > Owner / Obligee Services > Validate Bond Coverage, if you want to verify bond authenticity.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Drive DeVilbiss Healthcare MDEG License # (if applicable) _____

Physical Address 500 Palmetto Logistics Pkwy

City Palmetto State GA Zip 30349

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone [redacted] Website www.drivemedical.com

Licensing Company Email _____

Section 2: Personal Information

First William Middle _____ Last Waller

Alias(es, nicknames, name changes, etc.) Chase

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Newnan State GA Zip 30265

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hanford High School		09/2002 - 06/2006	
Address	**City**	**State**	**Zip**
450 Hanford St	Richland	WA	99354
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 - 04/24	[redacted]	[redacted]	GA	30265
10/12 - 07/19			WA	99301

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Drive DeVilbiss Healthcare			03/19 - 04/24	
Business Address		**City**	**State**	**Zip**
500 Palmetto Logistics Pkwy		Palmetto	GA	30265
Phone	**Title**		**Number of Employed Hours**	
(404) 349-0280	DIrector of Operations		10,000	
Description of Duties				
Manage, oversee and plan Operations activities for warehouse distribution facility.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, William Waller, **certify that as the MDEG Administrator for**

Drive DeVilbiss Healthcare,

that I (initial that you have read and meet the following requirements):

1. WW Have a high school diploma or its equivalent;
2. WW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. WW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. WW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Waller
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/9/2024
Date

Board Use Only	Date Received: 5/9/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medical Depot Inc. dba Drive DeVilbiss Healthcare

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 500 Palmetto Logistics Parkway

City: Palmetto State: GA Zip: 30265

Mailing Address (if different from physical address): 99 Seaview Blvd

City: Port Washington State: NY Zip: 11050

Telephone: 5169984600 Website: www.drivemedical.com

Licensing Company Email: licensing@drivemedical.com

Section 2: Personal Information

First: William Middle: C Last: Waller

Alias(es, nicknames, name changes, etc.): [redacted]

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: GA Zip: 30265

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hanford High School			
Address	**City**	**State**	**Zip**
450 Hanford St	Richland	WA	99352
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 - 03/24	[redacted]	[redacted]	GA	30265
10/12 - 07/19			WA	99301
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Drive Devilbiss			03/19 - 03/24	
Business Address		**City**	**State**	**Zip**
500 Palmetto Logistics Pkwy		Palmetto	GA	30349
Phone	**Title**		**Number of Employed Hours**	
4043490280	Director of Operations		10,400	
Description of Duties				
Oversee and plan all aspects of operation.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, William Waller, **certify that as the designated representative for**

Drive Devilbiss Healthcare - Palmetto, GA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WW I am at least 21 years of age;
3. WW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

William Waller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/13/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Waller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Fulton

I, William Waller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/15/24

Date

Subscribed and Sworn to before me this 15th day of March.

Notary Public Signature

JACQUELYN WRIGHT NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES AUGUST 25, 2025

Payroll Name	Job Title Description	Hire/Rehire Date	Location Description
Carter, Bonnie J	Production Associate	[redacted]	Atlanta DC
Floyd, James Maurice	Receiving Operator		Atlanta DC
Jackson, Stacie N	Team Lead		Atlanta DC
Jenkins, Darren	Returns Clerk		Atlanta DC
Price, Brandon	Order Picker		Atlanta DC
White , William Anthony	Production Associate		Atlanta DC
Wilder, Shandra	Team Lead		Atlanta DC
McNeil, Antione D	Manager, Corp Environmental, Health & Safety		Atlanta DC
Cabrera, Kevin	QC Inspector		Atlanta DC
Miller, Travis M	Lead Quality Control Inspector		Atlanta DC
Williams, Akealia Latrell	QC Inspector		Atlanta DC
Emery, Ashton J.M.	Warehouse Administrator		Atlanta DC
Galvez, Rocio De los Angeles	Auditor/Biller		Atlanta DC
Hart, Semaj	Order Picker		Atlanta DC
Jackson, Felande	Inventory Researcher		Atlanta DC
Mcginty, Sharrod	Order Picker		Atlanta DC
Ortiz Herrera, Francisca	Auditor/Biller		Atlanta DC
Ovalles Guzman, Jesus M	Order Picker		Atlanta DC
Romero, Juan	Operations Manager		Atlanta DC
Turner II, Douglas L	Warehouse Administrator		Atlanta DC
Young, Samantha	Team Lead		Atlanta DC
Clay, Eric	Housekeeping		Atlanta DC
Dean, Arnesha	Operations Manager		Atlanta DC
Hernandez-Perez, Luis D	Supervisor (DCs)		Atlanta DC
Holloway, Allen Junior	Maintenance Technician		Atlanta DC
Lavacca, Mark	VP, NA Operations		Atlanta DC
Lindsey, Lorenzo	Supervisor (DCs)		Atlanta DC
Munoz, Johanna	Operations Manager		Atlanta DC
Paige, Sheena	Supervisor (DCs)		Atlanta DC
Phillips, Katrese	Housekeeping		Atlanta DC
Ramirez, Ambrosia	Housekeeping		Atlanta DC
Ramos, Marcos	Operations Manager		Atlanta DC

Rener, Mychelle L	Supervisor (DCs)	[redacted]	Atlanta DC
Rener, Mychay L	Supervisor (DCs)		Atlanta DC
Slaton, Lekeita	Administrative Assistant		Atlanta DC
Vaughn, Frederick Taylor	Warehouse Data Analyst		Atlanta DC
Waller, William	Director of Operations		Atlanta DC
Whitworth, Jeffrey Andrew	Facility Manager - (DCs)		Atlanta DC
Williams, Kayla Nicole	Supervisor (DCs)		Atlanta DC
Alvarez, Estefania Monserratt	Team Lead		Atlanta DC
Arnold, Lorenzo D	Team Lead		Atlanta DC
Barnes, Latonya	Cycle Counter - DCs		Atlanta DC
Carroll, Michael	Inventory Researcher		Atlanta DC
Gooden, Patrick	Cycle Counter - DCs		Atlanta DC
Gordon, Giovonni	Replenisher		Atlanta DC
Hernandez-Perez, Jose L	Cycle Counter - DCs		Atlanta DC
Jones, ZiAndria	Cycle Counter - DCs		Atlanta DC
Rainey, Harold	Replenisher		Atlanta DC
Reid, Lloyd C	Replenisher		Atlanta DC
Williams, Johnnie	Replenisher		Atlanta DC
Battle, Tiffany	Team Lead		Atlanta DC
Becks, Bryan	Warehouse Administrator		Atlanta DC
Blanchard deBrown, Belgica B	Receiving Operator		Atlanta DC
Bowen, Tia	Auditor/Biller		Atlanta DC
Collier, Kirby	Receiving Operator		Atlanta DC
Dorsey, Dejuante	Receiving Operator		Atlanta DC
Elder, Jaliyah	Auditor/Biller		Atlanta DC
Flores, Francisco	Team Lead		Atlanta DC
Garcia, Maria A	Auditor/Biller		Atlanta DC
Hernandez Perez, Luis Javier	Inventory Researcher		Atlanta DC
LeBlanc, Kenneth	Order Picker		Atlanta DC
Lopez Villalobos, Elder Joel	Team Lead		Atlanta DC
Massey, William E	Receiving Operator		Atlanta DC
McDonald, Michael	Receiving Operator		Atlanta DC
Morell-Reyes, Carlos M	Replenisher		Atlanta DC

Mosley, Halle	Warehouse Administrator	[redacted]	Atlanta DC
Talley, Tavorick lamarzo	Receiving Operator		Atlanta DC
White, Brandon	Receiving Operator		Atlanta DC
Williams, Ricky L	Receiving Operator		Atlanta DC
Williams, Prince	Receiving Operator		Atlanta DC
Anderson, Quinton	Loader		Atlanta DC
Barnes, Isaac A	Order Picker		Atlanta DC
Blanding, Deshawn	Order Picker		Atlanta DC
Bone, Walter	Loader		Atlanta DC
Bonilla, Karen Marlene	Auditor/Biller		Atlanta DC
Brooks, Lawrence	Order Picker		Atlanta DC
Brown, Shantal	Auditor/Biller		Atlanta DC
Brown, Tysha	Order Picker		Atlanta DC
Cabrera Coto, Oscar	Order Picker		Atlanta DC
Canales, Suleyvia	Auditor/Biller		Atlanta DC
Canales, Denilson Omar	Auditor/Biller		Atlanta DC
Carson, Kendell	Loader		Atlanta DC
Cato, Contrella	Auditor/Biller		Atlanta DC
Clark, Anthony R	Order Picker		Atlanta DC
Clark, Anthony Jamez	Order Picker		Atlanta DC
Cofer, Robert	Order Picker		Atlanta DC
Coleman, Constance L	Order Picker		Atlanta DC
Cooper IV, Durant	Loader		Atlanta DC
Cruz, Ernesto	Receiving Operator		Atlanta DC
Cullens, Demonte	Order Picker		Atlanta DC
Cummings, Fredarius	Order Picker		Atlanta DC
Daniels, Hirram Delbert	Order Picker		Atlanta DC
David, Devin	Auditor/Biller		Atlanta DC
De Paz De Morales, Jeymy	Auditor/Biller		Atlanta DC
De Paz Leon, Ronald A	Auditor/Biller		Atlanta DC
Delgado, Deborah A	Auditor/Biller		Atlanta DC
Dent, Douglas	Order Picker		Atlanta DC
Elom, Terence	Order Picker		Atlanta DC

Elzy, Amari	Auditor/Biller	[redacted]	Atlanta DC
Everette, Ashley	Auditor/Biller		Atlanta DC
Feliz Suero, Sandra	Auditor/Biller		Atlanta DC
Figueroa, Stephany	Auditor/Biller		Atlanta DC
Figueroa, Claudia	Auditor/Biller		Atlanta DC
Gaskins, Antonia	Auditor/Biller		Atlanta DC
Gates, Martes	Order Picker		Atlanta DC
Glasco, Letitia	Auditor/Biller		Atlanta DC
Glenn, Calandra	Auditor/Biller		Atlanta DC
Graham, Earl	Order Picker		Atlanta DC
Green, Kenneth	Order Picker		Atlanta DC
Green, Epps	Order Picker		Atlanta DC
Harps, Manquavious	Order Picker		Atlanta DC
Harris, Anguyst Q	Loader		Atlanta DC
Hawkins, Tamika	Warehouse Administrator		Atlanta DC
Haywood, Rahshan	Order Picker		Atlanta DC
Hebert, William Maurice	Auditor/Biller		Atlanta DC
Heyward, Isaac	Receiving Operator		Atlanta DC
Hill, Leoary	Order Picker		Atlanta DC
Hinton, Derious	Order Picker		Atlanta DC
Horner, Martin	Loader		Atlanta DC
Howard, Ebony	Order Picker		Atlanta DC
Howard, Devon Shamir	Loader		Atlanta DC
Jackson, Delone A	Replenisher		Atlanta DC
Jimenez, Karla Arelis	Auditor/Biller		Atlanta DC
Johnson, Jarrel	Loader		Atlanta DC
Leon Figueroa, Yanely	Auditor/Biller		Atlanta DC
Lopez, Luis J	Loader		Atlanta DC
Maiden, Nujoye Christopher	Order Picker		Atlanta DC
Major, Aron Jermaine	Order Picker		Atlanta DC
Malone, Latoshia	Auditor/Biller		Atlanta DC
McDaniel, Ingrid D	Team Lead		Atlanta DC
McDowell, Terence	Receiving Operator		Atlanta DC

McRae, Solarian	Order Picker	[redacted]	Atlanta DC
Mcgill, Tamesha	Auditor/Biller		Atlanta DC
Mendoza, Richard Joel	Order Picker		Atlanta DC
Miller, Angela	Auditor/Biller		Atlanta DC
Minter, TeQuia	Auditor/Biller		Atlanta DC
Mitchell, Sierra Nicole	Team Lead		Atlanta DC
Mosley, Roderick	Loader		Atlanta DC
O'Dell, Bianca	Auditor/Biller		Atlanta DC
Obando Mejia, Andres Felipe	Loader		Atlanta DC
Oduro, Felix	Loader		Atlanta DC
Orr, Kristy	Auditor/Biller		Atlanta DC
Peralta Rodriguez, Eduardo A	Loader		Atlanta DC
Pickens, Ronald	Order Picker		Atlanta DC
Reese, Lester	Order Picker		Atlanta DC
Reina, Maria	Auditor/Biller		Atlanta DC
Rhodes, Kenyatita	Order Picker		Atlanta DC
Rodriguez Lara, Sarahi	Auditor/Biller		Atlanta DC
Rodriguez Lara, Laura	Auditor/Biller		Atlanta DC
Rolle, Joel D.	Order Picker		Atlanta DC
Romero, Sohaiti Aida	Team Lead		Atlanta DC
Romero Ovalles, Hilmary	Auditor/Biller		Atlanta DC
Salinas, Yessica Y	Team Lead		Atlanta DC
Sanchez, Blanca	Auditor/Biller		Atlanta DC
Santana, Darlenys	Warehouse Administrator		Atlanta DC
Santana Almonte, Darielys	Team Lead		Atlanta DC
Simmons, Marquise	Order Picker		Atlanta DC
Smith, Sedrick L	Order Picker		Atlanta DC
Smith, Gerald	Order Picker		Atlanta DC
Smith, Andrew	Order Picker		Atlanta DC
Solomon, Kenneth	Order Picker		Atlanta DC
Stodghill, Donta	Order Picker		Atlanta DC
Swinney, Gary	Loader		Atlanta DC
Thomas, Kenneth Jamel	Order Picker		Atlanta DC

Thomas, Autumn	Auditor/Biller	[redacted]	Atlanta DC
Thompson, Gerard	Loader		Atlanta DC
Tolentino De Morel, Yenifer C	Auditor/Biller		Atlanta DC
Torres, Maritza Ileana	Biller		Atlanta DC
Tucker, Teeola	Auditor/Biller		Atlanta DC
Vargas Blanco, Yngrid Altagracia	Auditor/Biller		Atlanta DC
Velez, Luis Edelmiro	Loader		Atlanta DC
Walker, Lashuanta R	Auditor/Biller		Atlanta DC
Walters, David	Order Picker		Atlanta DC
Watson, Steven	Order Picker		Atlanta DC
Weaver, Dexter	Loader		Atlanta DC
Whitfield, Latrisa	Auditor/Biller		Atlanta DC
Wiley, Sharquitta A	Team Lead		Atlanta DC
Williams, Karinda	Loader		Atlanta DC
Word, Melvin	Supervisor (DCs)		Atlanta DC
Zachery, Dedric	Order Picker		Atlanta DC

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Drive DeVilbiss Healthcare

Physical Address: 200 Docks Corner Rd

City: South Brunswick State: NJ Zip: 08810

Mailing Address (if different from physical address): 99 Seaview Blvd

City: Port Washington State: NY Zip: 11050

Telephone: 516-998-4600 Website: www.drivemedical.com

Name of Designated Representative (DR): Dianne Alford

Licensing Company Email: _____ DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: DME	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: State Medical
Address: 3950 E. Sunset road #112 City: Las Vegas State: NV Zip: 89120

Name: Professional Medical
Address: 5450 Mill Street #101 City: Reno State: NV Zip: 89502

Name: Vegas Medical Supplies
Address: 3111 S. Valley View blvd #A-105 City: Las Vegas State: NV Zip: 89102

Name: Sierra Healthcare
Address: 6720 Placid street City: Las Vegas State: NV Zip: 89119

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Medical Depot Holdings, Inc
Corporation/Organization Name: Medical Depot Inc. DBA Drive DeVilbiss Healthcare
Mailing Address: 99 Seaview Blvd.
City: Port Washington State: NY Zip: 11050
Telephone: 5169984600 Email: licensing@drivemedical.com
Contact Person Name: Zita Yurko

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Drive DeVilbiss Healthcare

Facility Name

Dionne Alford

Print Name of Authorized Person Submitting Application

Dionne Alford

Original signature of Authorized Person (copies or stamps not accepted)

5/16/24

Date

Board Use Only	Date Received: 7/9/24	Amount: CC ✓

DeVilbiss® HEALTHCARE
100 DeVilbiss Drive
Somerset, PA 15501 USA
800.338.1988 • 814.443.4881
www.DeVilbissHealthcare.com

Director:

- Derek Lampert

Officers:

- Chief Executive Officer & President – Derek Lampert
- Secretary – Nora Coleman

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DEVILBISS HEALTHCARE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DEVILBISS HEALTHCARE LLC" WAS FORMED ON THE SIXTEENTH DAY OF MARCH, A.D. 2009.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4665257 8300

SR# 20241151785

Authentication: 203103587

Date: 03-25-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0751151

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

99 SEAVIEW BLVD PORT WASHINGTON, NY 11050-
500 PALMETTO LOGISTICS PKWY ATLANTA,GA 30349-
200 DOCKS CORNER RD SOUTH BRUNSWICK, NJ 08852-

Reg. No. 5004723

MEDICAL DEPOT INC
DRIVE DEVILBISS HEALTHCARE
99 SEAVIEW BLVD STE 210
PORT WASHINGTON, NY 11050-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0751139

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

100 DEVILBISS DR SOMERSET, PA 15501-
401 LEONARD BLVD N LEHIGH ACRES,FL 33971-

Reg. No. 5005714

MEDICAL DEPOT, INC.
DRIVE DEVILBISS HEALTHCARE
99 SEAVIEW BLVD, STE 210
PORT WASHINGTON, NY 11050-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

drive
DeVilbiss HEALTHCARE

Corporate Office
99 Seaview Blvd., Port Washington, NY 11050
Toll Free: 877.224.0946 • 516.998.4600
www.drivemedical.com

Ownership Information

(1) full legal name
Medical Depot Holdings, Inc.

(2) Federal Employer Identification Number
11-3525013

(3) mailing address
99 Seaview Blvd., Ste 210
Port Washington, NY 11050

(4) telephone number
516-998-4600

(5) percentage of ownership or fraction thereof, and (6) an accounting for 100% of the ownership of the organization

100%

Corporate Office
99 Seaview Blvd., Port Washington, NY 11050
Toll Free: 877.224.0946 • 516.998.4600
www.drivemedical.com

Ownership

Medical Depot Holdings, Inc.,

99 Seaview Blvd
Port Washington, NY 11050
Nassau County

Phone: 516-998-4600

FEIN: 46-3740994

100% owner

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/19/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Christine M Zinoman, CPCU, AIC
Arthur J. Gallagher Risk Management Services, LLC 30 Century Hill Drive Suite 200 Latham NY 12110	PHONE (A/C, No, Ext): 518-724-6734 FAX (A/C, No): 518-869-3580 E-MAIL ADDRESS: Chris_Zinoman@ajg.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Great Northern Insurance Company	20303
INSURER C : Chubb Custom Insurance	38989
INSURER D : Great American Assurance Company	26344
INSURER E : Crum & Forster Specialty Insurance Co	44520
INSURER F : Travelers Indemnity Co of America	25666

INSURED
Medical Depot, Inc dba
Drive DeVilbiss Healthcare
99 Seaview Blvd.
Port Washington NY 11050

COVERAGES **CERTIFICATE NUMBER:** 1483350240 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			36032032	9/15/2023	9/15/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ **SEE BELOW** $
B	AUTOMOBILE LIABILITY X ANY AUTO X OWNED AUTOS ONLY [X] SCHEDULED AUTOS X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73599666	9/15/2023	9/15/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A E	X UMBRELLA LIAB [X] OCCUR X EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 10,000 (U)			78186106 SEO126055	9/15/2023 9/15/2023	9/15/2024 9/15/2024	EACH OCCURRENCE AGGREGATE $	$ *25,000,000 $ *25,000,000 $ *SEE BELOW
F F	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB9K7419582351K UB9K2932542351R	10/6/2023 10/6/2023	10/6/2024 10/6/2024	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C D	PRODUCTS LIAB EXCESS LIAB EXCESS LIAB			36059025 EXC5126067	9/15/2023 9/15/2023	9/15/2024 9/15/2024	$10 Mil Ea Event/Agg $10 Mil x $25 Mil $15 Mil x $35 Mil	**SEE BELOW

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Insured - Blanket per Written Contract or Agreement Form 80-02-2367 (Rev 5-07)
Insured - Vendors - Liability Insurance Form 80-02-2085 (Ed 11-09)
Insured - Lessors of Premises Liability Insurance Form 80-02-2002 (Rev 4-01)
INSURER CODE E = Westfield Specialty Ins. Co, NAIC 24112, Policy # XSL00017HP01 + Crum & Forster Specialty Insurance Co Policy # SEO126055
INSURER CODE F = Travelers Indemnity Company of America and Travelers Property Casualty Co of America
*Total $25 Mil = $10 Mil Federal/Chubb Plus Quota Share Total of $15 Mil x $10 Mil [Each carrier $7.5 Mil part of $15 Mil Excess Liability]
**Excess Liability $15 Mil x $35 Mil with Endurance American Specialty Insurance Company Policy No ELD30001977103 eff 9/15/23 - 9/15/24
****NAMED INSURED****: Medical Depot, Inc dba Drive DeVilbiss Healthcare and its affiliates re:
See Attached...

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Arthur J. Gallagher Risk Management Services, LLC	Medical Depot, Inc dba Drive DeVilbiss Healthcare 99 Seaview Blvd. Port Washington NY 11050
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: CERTIFICATE OF LIABILITY INSURANCE

Drive DeVilbiss Healthcare, Palmetto, GA
Drive DeVilbiss Healthcare, South Brunswick, NJ
Inovo Inc., Lehigh Acres, FL
DeVilbiss Healthcare LLC, Somerset, PA

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30212202

Application/License No. PLEASE COMPLETE

Medical Depot Holdings, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 200 Docks Corner Road, Suite 241, South Brunswick, NJ 08810 (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is c/o CNA Surety, 151 N. Franklin St., Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 21st, 2024 (Effective Date),

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of July, 2024.

APPLICANT/PRINCIPAL

Medical Depot Holdings, Inc.

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Jaymie Patricia Columbus, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kimberly A. Ritchie

Witness Kayley Klinkel

Countersigned by:

N/A
Nevada Resident Agent

INDIVIDUAL

STATE OF _____ }
COUNTY OF _____ } ss

On this _____ day of _____, _____, before me personally appeared _____ to me known and known to me to be the individual in and who executed the foregoing instrument and _____ acknowledged to me that _____ executed the same in his individual capacity.

_____
Notary Public

COPARTNERSHIP

STATE OF _____ }
COUNTY OF _____ } ss

On this _____ day of _____, _____, before me personally appeared _____ to me known and known to me to be one of the firm of _____ described in and who executed the foregoing instrument and he/she thereupon acknowledged to me that he/she executed the same as and for the act and deed of said firm.

_____
Notary Public

CORPORATE

STATE OF New York }
COUNTY OF Nassau } ss

On this 17 day of July, 2024, before me personally appeared Nora Coleman to me known, who, being by me first duly sworn, did depose and say that he/she resides in Port Washington, NY; that he/she is the EVP, General Counsel + Secty of Drive DeVilbiss Healthcare + MEDICAL Depot Holdings, Inc. the corporation described in and which executed the foregoing instrument; that he/she knows the corporate seal of said corporation; that [illegible] said instrument is such corporate seal; that it was so affixed by order and authority of the Board of Directors of said corporation, and that he/she signed his/her name thereto by like order and authority.

BARBARA J MAROLDA
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01MA6080056
Qualified in Albany County
Commission Expires 03/23/2028

Barbara J Maroldа
Notary Public

SURETY

STATE OF NEW YORK }
COUNTY OF ALBANY } ss

I, Kimberly A. Ritchie Notary Public of Rensselaer County, in the State of New York do hereby certify that Jaymie Patricia Columbus Attorney-in-Fact, of the Western Surety Company, who is personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me this day in person, and acknowledged that he/she signed, sealed and delivered said instrument, for and on behalf of the Western Surety Company, for the uses and purposes therein set forth.

Given under my hand and notarial seal at my office in the City of Latham in said County, this 16th day of July, A.D. 2024.

KIMBERLY A. RITCHIE
Notary Public, State of New York
No. 01RI6215612
Qualified in Rensselaer County
Commission Expires January 4, 2026

Kimberly A. Ritchie
Notary Public

Form F5345

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2023

ASSETS

Bonds	$ 1,935,600,431
Stocks	15,281,696
Cash, cash equivalents, and short-term investments	36,335,353
Receivables for securities	14,770,000
Investment income due and accrued	18,185,645
Premiums and considerations	70,728,009
Amounts recoverable from reinsurers	4,459,042
Net deferred tax asset	18,202,272
Receivable from parent, subsidiaries, and affiliates	12,895,815
Other assets	157,742
Total Assets	$ 2,126,616,005

LIABILITIES AND SURPLUS

Losses	$ 247,328,673
Loss adjustment expense	56,340,495
Commissions payable, contingent commissions and other similar charges	13,245,319
Taxes, License and fees (excluding federal and foreign income taxes)	5,075,390
Federal and foreign income taxes payable	829,556
Unearned premiums	316,760,881
Advance premiums	6,183,112
Ceded reinsurance premiums payable (net of ceding commissions)	4,347,066
Amounts withheld or retained by company for account of others	3,094,680
Provision for reinsurance	157,388
Payable to parent, subsidiaries and affiliates	9,464
Other liabilities	(6,171)
Total Liabilities	$ 653,365,853

Surplus Account:		
Common stock	$ 4,000,000	
Gross paid in and contributed surplus	286,896,195	
Unassigned funds	1,182,353,957	
Surplus as regards policyholders		$ 1,473,250,152
Total Liabilities and Capital		$ 2,126,616,005

I, Julie Lee, Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2023, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Vice President, Accounting Policy & External Reporting

Subscribed and sworn to me this 14th day of March, 2024.

My commission expires:

YOLANDA JIMENEZ
OFFICIAL SEAL
Notary Public - State Of Illinois
My Commission Expires
September 24, 2025

By Yolanda Jimenez
Notary Public

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Michael Grasso, Charles C Leach, Jaymie Patricia Columbus, Kimberly Ritchie, Tiffany Gocha, Individually

of Latham, NY, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the Authorizing By-Laws and Resolutions printed at the bottom of this page, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 14th day of December, 2023.

WESTERN SURETY COMPANY

Larry Kasten, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 14th day of December, 2023, before me personally came Larry Kasten, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is a Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law and Resolutions of the corporation printed below this certificate are still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 16th day of July, 2024.

WESTERN SURETY COMPANY

L. Nelson, Assistant Secretary

Authorizing By-Laws and Resolutions

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

This Power of Attorney is signed by Larry Kasten, Vice President, who has been authorized pursuant to the above Bylaw to execute power of attorneys on behalf of Western Surety Company.

This Power of Attorney may be signed by digital signature and sealed by a digital or otherwise electronic-formatted corporate seal under and by the authority of the following Resolution adopted by the Board of Directors of the Company by unanimous written consent dated the 27th day of April, 2022:

"RESOLVED: That it is in the best interest of the Company to periodically ratify and confirm any corporate documents signed by digital signatures and to ratify and confirm the use of a digital or otherwise electronic-formatted corporate seal, each to be considered the act and deed of the Company."

Go to www.cnasurety.com > Owner / Obligee Services > Validate Bond Coverage, if you want to verify bond authenticity.

Gallagher
Insurance | Risk Management | Consulting

30 Century Hill Drive, Suite 200
Latham, NY 12110
United States

M - 518.869.3535
F - 518.869.3580
T - 888.869.3535
ajg.com

July 16, 2024

Ms. Judy Yeung
Drive DeVilbiss Healthcare
99 Seaview Blvd., Suite 210
Port Washington, NY 11050

Re: Bond No.: 30212201
Obligee: Nevada State Board of Pharmacy
Pharmaceutical Wholesaler Surety Bond
for Medical Depot Holdings, Inc. (Palmetto, GA)
Bond Amount: $100,000.00

Dear Judy,

Enclosed please find the above captioned ***REVISED*** Pharmaceutical Wholesaler Surety Bond which we ask that you have a corporate officer sign where indicated, have (2) witnesses sign where noted and have the notarial acknowledgment completed where shown.

Upon execution, please file the bond with the proper authorities. Thank you.

Very truly yours,

Jaymie Patricia Columbus
Client Service Supervisor
Surety Department

JPC/kar
Enclosures

Sent via UPS (07/16/2024)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medical Depot Inc. dba Drive DeVilbiss Healthcare — MDEG License # (if applicable): _____
Physical Address: 200 Docks Corner Rd. Suite 241
City: South Brunswick — State: NJ — Zip: 08810
Mailing Address (if different from physical address): 99 Seaview Blvd
City: Port Washington — State: NY — Zip: 11050
Telephone: 5169984600 — Website: www.drivemedical.com
Licensing Company Email: licensing@drivemedical.com

Section 2: Personal Information

First: Dionne — Middle: _____ — Last: Alford
Alias(es, nicknames, name changes, etc.): _____
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X
Mailing Address: [redacted]
City: North Brunswick — State: NJ — Zip: 08902
Telephon[redacted] — Email: [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Great Bridge High School		8/83-6/84	
Address	**City**	**State**	**Zip**
301 Hanbury Rd. W	Chesapeake	VA	23322
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
New Brunswick High School		9/81-6/83	
Address	**City**	**State**	**Zip**
100 Somerset St	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018-Present	[redacted]	North Brunswick	NJ	08902
From - To (MM/YY – MM/YY)		City	State	Zip
2007-2018		Hightstown	NJ	08520
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Drive DeVilbiss Healthcare				From - To (MM/YY – MM/YY): 12/2017-Present
Business Address: 200 Docks Corner Rd Suite 241		City: South Brunswick	State: NJ	Zip: 08810
Phone: 201-518-6052	Title: Director, Operations			Number of Employed Hours: 57,600
Description of Duties: Manages the company's senior- lever management.				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/6/24
Date

I, Dionne Alford, **certify that as the MDEG Administrator for**

Drive DeVilbiss Healthcare,

that I (initial that you have read and meet the following requirements):

1. DA Have a high school diploma or its equivalent;
2. DA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dionne Alford
Print Name (First, Last)

Dionne Alford
Original Signature (electronic, copies or stamps not accepted)

2/6/24
Date

Board Use Only	Date Received: 5/9/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medical Depot Inc. dba Drive DeVilbiss Healthcare

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 200 Docks Corner Rd. Suite 241

City: South Brunswick State: NJ Zip: 08810

Mailing Address (if different from physical address): 99 Seaview Blvd

City: Port Washington State: NY Zip: 11050

Telephone: 5169984600 Website: www.drivemedical.com

Licensing Company Email: licensing@drivemedical.com

Section 2: Personal Information

First: Dionne Middle: Last: Alford

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: North Brunswick State: NJ Zip: 08902

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Great Bridge High School			8/83-6/84	
Address		City	State	Zip
301 Hanbury Rd. W		Chesapeake	VA	23322
Diploma/Degree obtained, if any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
New Brunswick High School			9/81-6/83	
Address		City	State	Zip
100 Somerset St		New Brunswick	NJ	08901
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018-Present	[redacted]	North Brunswick	NJ	08902
From - To (MM/YY – MM/YY)		City	State	Zip
2007-2018		Hightstown	NJ	08520
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Drive DeVilbiss Healthcare				From - To (MM/YY – MM/YY): 12/2017-Present
Business Address: 200 Docks Corner Rd Suite 241		City: South Brunswick	State: NJ	Zip: 08810
Phone: 201-518-6052	Title: Director, Operations			Number of Employed Hours: 57,600
Description of Duties: Manages the company's senior- lever management.				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/6/24
Date

I, Dionne Alford, **certify that as the designated representative for**

Drive DeVilbiss Healthcare,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DA I am at least 21 years of age;
3. DA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dionne Alford

Print Name (First, Last)

Dionne

Original Signature (electronic, copies or stamps not accepted)

2/6/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dionne Alford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/6/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Dionne ALFORD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/6/24

Date

Subscribed and Sworn to before me this 6 day of Feb 2024

Notary Public Signature

YASHIRA M TROCHE NIEVES
Notary Public
State of New Jersey
My Commission Expires Dec. 7, 2028
I.D.# 2458643

(Seal)

Payroll Name	Job Title Description	Hire/Rehire Da	Location Description
Chan, Andrew	QC Inspector	07/01/2014	New Jersey
Colella, Gabrielle	QC Inspector	03/07/2022	New Jersey
Diaz, Angela	Team Lead	12/14/2014	New Jersey
LaPadura, Richard A	Returns Production Associate	04/08/2019	New Jersey
Alford, Dionne	Director of Operations	12/19/2017	New Jersey
Chaudhari, Narendrakumar G	Supervisor (DCs)	07/16/2018	New Jersey
Checo Rodriguez, Lisbel	Warehouse Administrator	09/16/2019	New Jersey
Deol, Jatinder S	Operations Manager	07/30/2018	New Jersey
Hearn, Sadell	Supervisor, Inventory	06/06/2022	New Jersey
Pillai, Sudha	Warehouse Administrator	05/19/2021	New Jersey
Rothacre, Nicole	Supervisor (DCs)	12/28/2020	New Jersey
Sarcone, Michael H	Maintenance Technician	01/25/2016	New Jersey
Delgado, Gladys B	Cycle Counter - DCs	06/24/2013	New Jersey
Guzman, Juan E	Replenisher	07/13/2012	New Jersey
Loaiza, Orlando	Replenisher	07/02/2018	New Jersey
Mendoza Rivera, Araceli	Cycle Counter - DCs	08/29/2016	New Jersey
Sagbay, Bryan F	Team Lead	01/13/2019	New Jersey
Lobo, Jose	Replenisher	09/11/2002	New Jersey
Quizhpi, Carlos E	Receiving Operator	02/26/2018	New Jersey
Ramirez Ramos, Joanna	Team Lead	05/04/2015	New Jersey
Ramos, Jose R	Replenisher	02/10/2014	New Jersey
Torres, Joel	Receiving Operator	10/26/2011	New Jersey
Abreu, Maria M	Auditor/Biller	10/31/2016	New Jersey
Alvarez, Jose	Order Picker	01/02/2018	New Jersey
Andahua Urbano, Gloria Maria	Auditor/Biller	11/29/2023	New Jersey
Augustine, Francisco P	Replenisher	05/18/2015	New Jersey
Batista-Moreta, Santa	Auditor/Biller	08/31/2015	New Jersey
Bentsil, David O	Loader	03/25/2019	New Jersey
Bonilla, Oscar J	Team Lead	04/26/2019	New Jersey
De León Dominguez, Zoila	Auditor/Biller	05/20/2024	New Jersey
Donaghy, Kevin	Loader	10/23/2023	New Jersey
Donnoli, Michael V	Order Picker	10/01/2018	New Jersey
Garva, Nayel Eduardo	Order Picker	02/20/2024	New Jersey
Gutierrez, Maria	Auditor/Biller	03/09/2022	New Jersey
Hernandez Ixcot, Benito Juan	Order Picker	10/17/2022	New Jersey
Jaquez, Pablo A	Order Picker	07/23/2018	New Jersey
Lewis, Rajahn	Replenisher	12/20/2021	New Jersey
Lopez Benjumea, Gloria E	Auditor/Biller	08/31/2015	New Jersey
Martinez, Tania Lariza	Auditor/Biller	05/06/2024	New Jersey
Ocharan Vidal, David	Order Picker	01/15/2018	New Jersey
Patel, Rameshbhai I	Auditor/Biller	07/02/2018	New Jersey
Paucar, Raul	Order Picker	10/06/2021	New Jersey
Pavlonnis, Theodore	Order Picker	11/09/2022	New Jersey

Peralta De Pineda, Sandra Y	Auditor/Biller	04/01/2019	New Jersey
Quito, Jonnathan	Order Picker	09/23/2021	New Jersey
Ready, Zachary	Supervisor (DCs)	06/26/2023	New Jersey
Rodriguez, Wilmar Eduardo	Order Picker	11/15/2023	New Jersey
Rodriguez, Gerardo	Order Picker	04/01/2024	New Jersey
Tapia, Javier	Team Lead	01/06/2014	New Jersey
Tello, Andrea L	Auditor/Biller	12/16/2018	New Jersey
Torres, Jeffrey M	Loader	11/07/2022	New Jersey
Turell-Martinez, Heriberto	Loader	02/08/2016	New Jersey
Valle, Jerson aldair	Order Picker	05/28/2024	New Jersey
Villacis Morocho, Mayra A	Receiving Operator	01/15/2018	New Jersey
Viva Duran, Deisi Lucrecia	Auditor/Biller	05/05/2019	New Jersey
Woods, Karl	Order Picker	10/31/2011	New Jersey

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Pharmaceutical Trade Services Inc. DBA Uniphar DBA Uniphar Clinical DBA Durbin USA

Physical Address: 5100 Jones Sausage Road, Suite 140

City: Garner State: NC Zip: 27529

Mailing Address (if different from physical address): (Same)

City: _____ State: _____ Zip: _____

Telephone: 888-683-2819 Website: www.unipharclinical.com

Name of Designated Representative (DR): Angela Humrich

Licensing Company Email: N/A DR Email: [redacted]

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	■ Controlled Substances	■ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2021	MS	Ocean Springs	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		DEA		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached statement regarding Civil Settlement related to PTSI MS facility, not the NC facility which is subject of this application (wish to be transparent and forthcoming).

Original Signature (electronic, copies or stamps not accepted)

14AUG2024

Date

Pharmaceutical Trade Services Inc. Statement regarding Question 3 on PTSI Application.

Pharmaceutical Trade Services, Inc. DBA Durbin USA Mississippi Facility in 2021 reached a Civil settlement with the US DEA resulting in paying a fine of $175,000.00 and entering into a 3 (three) year MOA, copy of which is attached. This 2021 Agreement was neither an admission of liability by PTSI nor a concession by the United States that its claims are not well founded and was regarded record keeping issues concerning Controlled Substance distribution. After the inspection which brought these issues to light and lead to this settlement, PTSI MS Facility conducted extensive review and implemented new processes. PTSI MS Facility was again audited by the DEA in March 2023 with no deficiencies noted and by MS Board of Pharmacy in September 2023 without any findings against their MS CS licenses (see attached copy MS Inspection Form).

While this Civil Settlement *does not apply to* the same Facility that is the subject of this application, PTSI wanted to be forthcoming regarding this settlement and the proactive steps taken to correct the issues involved.

PTSI North Carolina Facility (the Facility subject of this application) intends to apply for Controlled Substance licenses and DEA Certification in Q4 2024 and will be implementing such policies and procedures, along with conducting employee training, to meet all DEA and State requirements so as to conduct CS distribution with exemplary high standards.

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the U.S. Department of Justice and on behalf of the U.S. Drug Enforcement Administration (collectively "the United States") and Pharmaceutical Trade Services, Inc. d/b/a Durbin USA ("Durbin") (collectively referred to hereinafter as "the Parties"), through their authorized representatives.

1. The United States has informed Durbin that from facts now available to the U.S. Department of Justice, Durbin's conduct during the period from August 7, 2013, through August 7, 2020, may give rise to civil liability under certain laws and regulations of the United States, including the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* and its associated regulations and common law.

2. The United States has determined that it has good cause to initiate a civil action alleging certain claims and causes of action against Durbin based on the Comprehensive Drug Abuse and Control Act of 1970, for monetary penalties as a result of violations of, *inter alia*, 21 U.S.C. §§ 827(a), 828(a), 842(a), and 843(a) and 21 C.F.R. §§ 1304.11, 1304.21, 1304.22, 1305.03, and 1305.12. This Agreement is neither an admission of liability or fact by Durbin, nor an admission of agreement as to the United States' alleged cause, nor a concession by the United States that its claims are not well founded.

3. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in accordance with the mutual covenants and agreements made herein, the Parties, with full authority to enter into this Agreement and to be bound thereby, agree that, on or before November 30, 2021,

Durbin shall pay to the United States the sum total of $175,000.00 (hereinafter "debt"). No interest shall be incurred from the date of the Agreement through November 30, 2021.

a. Such debt shall be paid in the form of a certified or cashier's check or via Fedwire. If payment is made via Fedwire, it shall be in accordance with the instructions provided by the United States. If payment is made via certified or cashier's check, it shall be payable to the United States Department of Justice, shall include "Pharmaceutical Trade Services, Inc. d/b/a Durbin USA case number ___"[1] in the memo line of the check, and shall be delivered to

U.S. Department of Justice
Nationwide Central Intake Facility
P.O. Box 790363
St. Louis, MO 63179-0363

b. Upon execution of this Agreement, the total debt will be placed on the Treasury Offset Program ("TOP"), and Durbin agrees to the offset and application of any tax refunds or other payments from the U.S. Treasury to which Durbin may be entitled until the debt is paid in full. Once the debt is paid in full, the United States will promptly remove the debt from the TOP and no offset shall be made.

4. Durbin agrees to enter into a Memorandum of Agreement with the U.S. Drug Enforcement Administration. The Memorandum of Agreement is attached to this Agreement and made a part hereof.

5. In consideration of the full and timely payment of the sum agreed upon in

[1] The "case number" will be provided by the United States to Durbin in a separate communication.

Paragraph 3 of this Agreement and execution of the Memorandum of Agreement described in Paragraph 4 of this Agreement, the United States waives and releases Durbin, its parent entities, subsidiaries, affiliates, successors, and assigns, and promises to refrain from instituting any criminal, civil, or administrative claim, action, charge, suit, or proceeding by or on behalf of the Drug Enforcement Administration arising from the specific matters set forth in this Agreement against Durbin, its parent entities, subsidiaries, affiliates, successors, and assigns.

6. Notwithstanding the release given in paragraph 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and not released:

    a. any liability arising under Title 26 of the United States Code (Internal Revenue Code) and/or

    b. any liability based upon obligations created by this Agreement.

7. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without compulsion. Each party is represented by counsel.

8. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Mississippi. For purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and therefore shall not be construed against any Party for that reason in any subsequent dispute.

9. Should Durbin subsequently be determined to have violated the terms and conditions of this Agreement, Durbin shall be liable to the United States for any

costs and attorneys' fees incurred by the United States in any action for noncompliance with this Agreement.

10. This Agreement constitutes the full and complete Agreement between the Parties, with respect to the matters covered herein, and no modification shall be effective unless in writing and signed by the Party against whom it is sought to be enforced.

11. This is a publicly available document, and Durbin waives any claim that this document along with any information contained herein is subject to the Privacy Act of 1974, 5 U.S.C. § 552a.

AGREED:

DARREN J. LAMARCA
Acting United States Attorney for
the Southern District of Mississippi

Jennifer Case
Assistant United States Attorney

10/21/2021
Date

Melissa McLaughlin [Printed name]
SVP [Title]
Pharmaceutical Trade Services, Inc. d/b/a
Durbin USA

10/20/2021
Date

Represented by Glenn Colton
Arent Fox LLP
Attorney for Pharmaceutical Trade Services, Inc.
d/b/a Durbin USA

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: PTSI NC Facility is not yet open, has not sold or distributed products.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Mississppi

Parent Company (if any): 100% holding company Durbin Inc which in turn is 100% owned by Uniphar plc (see org chart)

Corporation/Organization Name: Pharmecutical Trade Services, Inc. DBA Uniphar DBA Uniphar Clinical DBA Durbin USA

Mailing Address: 5100 Jones Sauage Road, Suite 140

City: Garner State: NC Zip: 27529

Telephone: 888-683-2819 Email: [redacted]

Contact Person Name: Mickelle Owens

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Pharmaceutical Trade Services, Inc. DBA Uniphar DBA Uniphar Clinical DBA Durbin USA
Facility Name

Angela Hummch
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

14AUG2024
Date

Board Use Only	Date Received: 9/24/24	Amount: $1000-CK76676

Company Officers

Pharmaceutical Trade Services Inc. DBA Uniphar DBA Uniphar Clinical DBA Durbin USA is part of the Uniphar Group, a global life science and pharmaceutical distribution company.

Pharmaceutical Trade Services Inc. **is opening a new wholesale drug distribution facility in North Carolina at 5100 Jones Sausage Road, Suite 140, Garner, NC 27529.**

Officers and Directors:

- President, Conor McCarthy, [redacted]
- Senior Vice President, Melissa McLaughlin, [redacted]
- US Head of Quality, Angela Humrich, [redacted]

Pharmaceutical Trade Services Inc. Organization Chart



2024

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
581

LICENSE/CERTIFICATE: Distributor
TYPE PRESCRIPTION DRUG LICENSE
Expiration Date 12/31/2024

ENSEE PHARMACEUTICAL TRADE SERVICES INC DBA
DURBIN USA DBA UNIPHAR CLINICAL DBA UNIPHAR
RTIFICATOR 5100 JONES SAUSAGE ROAD STE 140
GARNER NC 27529

LICENSED
2024
NORTH CAROLINA

IS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

1255

NORTH CAROLINA CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Department of Health and Human Services
Raleigh, North Carolina

THE N.C. Controlled Substances Act of 1971 reads in part as follows:

90-103(a): A registration under G.S. 90-102 to manufacture, distribute, or dispense a controlled substance, may be suspended or revoked by the Commission upon a finding that the registrant:

(1) has furnished false or fraudulent information in any application filed under this Article;

(2) has been convicted of a felony under any State or federal law relating to any controlled substance; or

(3) has had his federal registration suspended or revoked to manufacure, distribute or dispose controlled substances.

DHHS Registration Number		This Registration Expires
NC-DHHS-1005183		12/31/2025
Schedules	**Business Activity**	**Date Issued**
2, 2N, 3, 3N, 4, 5	Distributor	8/19/2024

Form DHHS-223

Department of Health and Human Services

Pharmaceutical Trade Services, Inc. dba Uniphar Clinical

5100 Jones Sausage Rd, Suite 140
Garner NC 27529

This registration is not transferable on change of ownership, control, location or business activity

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107881566

Application/License No. _____

Pharmaceutical Trade Services, Inc. dba Durbin USA (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5100 Jones Sausage Road ~ Garner, NC 27529 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square ~ Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 6, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 6th day of December, 20 23.

APPLICANT/PRINCIPAL

COMPANY
Pharmaceutical Trade Services, Inc.
dba Durbin USA

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Susan Skrmetta, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness
Kathleen Scarborough

Witness
Darlene Landry

Countersigned by:

Nevada Resident Agent

Kaley Campbell
10000 W. Charleston Blvd. Ste 200
Las Vegas, NV 89135

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Susan Skrmetta** of **GULFPORT**, **Mississippi**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **6th** day of **December**, **2023**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pharmaceutical Trade Services, Inc.

Pharmacy/Wholesaler License # (if applicable): TBD

Physical Address: 5100 Jones Sausage Road, Suite 140

City: Garner State: NC Zip: 27529

Mailing Address (if different from physical address): (Same)

City: State: Zip:

Telephone: 888-683-2819 Website: www.unipharclinical.com

Licensing Company Email: N/A

Section 2: Personal Information

First: Angela Middle: Kay Last: Humrich

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] Sta[redacted] Zip: 27616

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SEE ATTACHED RESUME			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2024- Current	[redacted]	[redacted]	NC	27616
7/2023-5/2024			PA	19444
10/2020-7/2023			ND	58059
8/2014-10/2020			ND	58104
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Please see attached Resume			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.



Angela
Calkins
HUMRICH
[redacted]

SUMMARY

› **OVER TWO DECADES OF EXCELLENCE IN BUILDING FORWARD-THINKING QUALITY, REGULATORY, AND COMPLIANCE (QRC) ORGANIZATIONS** which actively enables growth and safeguards against emerging areas of risk. Experience building sustainable corporate-wide Quality Management systems and creating a "right first time" culture.

› **A COLLABORATIVE AND TRANSPARENT LEADER** with a passion for realizing the untapped potential of our people and operations. Unafraid to forge consensus in conflict-ridden situations and capitalize on the "quick-win" on the road to deeper transformation. The ability to effectively build and maintain relationships across the organization to effectively solve problems.

SKILLS

- GxP, GDP
- CAPA
- Lean Six Sigma Green Belt
- Validation
- Regulatory Compliance
- SOP Development
- Change Control
- QMS Auditing
- Resource Allocation
- Process Improvement
- Budget Oversight
- Complex Problem-Solving
- Change and Growth Management
- Relationship and Team Building
- Leadership and People Development
- Integrity and Transparency

EXPERIENCE

US Head of Quality
Garner, NC
Uniphar Group/ Feb 2024 to Current

- Advised senior executives on approaches for resolving complex issues impacting operations
- Identified problems and implemented solutions to better streamline operations
- Communicated regularly with executive team members to deliver pertinent details related to progress status and direction for projects
- Conducted risk assessments to identify potential areas of non-compliance with regulatory requirements
- Collaborated with cross-functional teams to ensure that all processes are compliant with relevant regulations, oversight of day to day distribution operations

Vice President of Quality & Regulatory Affairs
Horsham, PA
Eurofins/ Aug 2022 to Feb 2024

- Reviewed blueprints, drawings and other specifications to fully understand project expectations
- Worked alongside developers and other project stakeholders to build out new GxP clinical packaging and labeling facility
- Augmented knowledge of ERP software and tools by actively participating in available trainings and workshops
- Implemented new ERP system to drive quality, consistency, and compliance within

Operations

- Explored new technologies and tools for productivity, security and quality assurance purposes

US Head of Quality & Regulatory Affairs
Fargo, ND
Clinigen Clinical Supplies Management Inc/ Feb 2003 to Aug 2022

- Established a robust Quality, Compliance and Risk Management organization driving 25%+YOY reductions in deviations and non-conformances, major improvements in data-driven decision making and attaining KPIs, and a truly forward-thinking approach towards addressing emerging areas of risk
- Served as a trusted partner to senior leadership in defining long-term strategy
- Provided Quality oversight to 4 facilities
- Designed and led the internal audit and inspection readiness program resulting in 6 successful regulatory inspections and 125 successful client audits over 2 years
- Forged strong working relationships with federal and state regulators and demonstrated a talent for moving past complex roadblocks
- Redefined the role of Quality as a key facilitator of overall growth
- Maintained full compliance with the FDA, ICH, DEA, NABP, USDA import/export permits, GxP regulatory standards, and state licensing requirements during a period of spiking customer demands
- Implemented global Quality Governance Meetings with client Quality to ensure all entities involved are on the same page
- Maintained full compliance with states ensuring the appropriate licenses were acquired for clinical trials and Direct-to-Patient activities
- Experienced with requirements of the USDA for importing from Ex-US countries
- Defined core quality goals and partnered with global Quality Directors on strategy-through-execution of major initiatives
- Led, mentored, and supported the need of Quality Assurance and Quality Systems team members
- Emphasized priorities which yield both ROI and enable Clinigen to become a fundamentally stronger and more sound organization for years to come
- Brought an entirely new level of data-driven decision-making into play through implementation of an electronic Quality Management System (eQMS) standardizing and harmonizing quality metrics, KPIs, and reporting across the entire company
- Created a quality compliance scorecard, and numerous assessment reporting tools for accurately gauging the effectiveness and inspection readiness of quality management systems
- Ensures alignment of global compliance activities to business activities with a focus on Growth, Innovation, and Operational Effectiveness across all functional areas
- Changed the Quality and Compliance organization's role from "putting out fires" into an active enabler of sustainable growth, including assessing internal and external areas of vulnerability
- Introduced a virtual audit platform with no paper for hosting onsite audits which enabled the transition for complete virtual audits during COVID

- Implemented a global Learning Management System and training program.

EDUCATION AND TRAINING

Bachelor of Science, B.S: Biochemistry & Biotechnology
Minnesota State University Moorhead May 2018
Moorhead, MN

Masters of Proficiency: Science
Minnesota State University Jan 2009
Moorhead, MN.
Ethics in the Biochemistry Biotechnology Industry, Introduction to Quality Assurance and Quality Control in the Biochemistry and Biotechnology Industry

Associate of Science: Pharmacy Technician
North Dakota State College of Science Jan 2005
Wahpeton, ND

Some College (No Degree): Mechanical Engineering
Wharton County Junior College
Wharton, TX

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Maria Herrera

From: Angela Humrich <[redacted]
Sent: Monday, September 30, 2024 8:39 AM
To: Maria Herrera
Subject: RE: Nevada Out-of-State Wholesaler Application-Durbin USA
Attachments: NC Certificate of Good Standing.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Maria,

Thank you for your reaching out.

I want to confirm that the application is for Pharmaceutical Trade Services, Inc. dba Uniphar Clinical.

I cannot provide any court documents as the incident occurred in August of 1989. I can attest that was the only occurrence.

Please find attached the Certificate of Good Standing.

If you need anything else, please reach out.

Best Regards,
Angela

Angela Calkins Humrich
US Head of Quality
Uniphar
Beacon Commerce Park
5100 Jones Sausage Rd, Ste 130 | Garner, North Carolina 27529

1268

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	ND

Reason/Charge
Reckless Driving 1988

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

please see attached

Original Signature (electronic, copies or stamps not accepted)

14 AUG 2024
Date

uniphar

durbin
part of the uniphar group

July 22, 2024

Explanation related to Designated Representative Question 1.

Please note 1988 Reckless Driving conviction listed on the enclosed FBI report. This is my sworn statement that is my only criminal conviction and that I am not the subject of any pending State or Federal criminal charges as of this date.

Best regards,

Angela Calkins Humrich

5100 Jones Sausage Road, Suite 140, Garner, NC 27520 888-683-2819

I, Angela Hummich, **certify that as the designated representative for**

PISI DBA Uniphar Clinical,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Angela Hummich

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

14 AUG 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Humrich
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

14 AUG 2024
Date

Please have this section completed in the presence of a Notary Public.

State of NC, ss. County of Wake

I, Angela Humrich, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

14 AUG 2024
Date

Subscribed and Sworn to before me this 14TH day of August 2024

Notary Public Signature COMMISSION: August 3, 2028

ELIZABETH CRAIN NOTARY PUBLIC WAKE COUNTY, NC

(Seal)

uniphar

President – Bob Albanese

Vice President, Global Client Contracts – Jennifer Lauinger

Vice President – Michael Bernstein

US Head of Quality – Angela Humrich

Quality Systems Manger – Mickelle Owens

Clinical Project Manager – Steve Purdy

Marketing & Operations Associate – Christos Michalopoulos

Operations Manager – Brian Pitchford

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Inspection Report

Pharmaceutical Trade Services Inc.
d/b/a Durbin USA, d/b/a Uniphar Clinical, d/b/a Uniphar
5100 Jones Sausage Road, Suite 140
Garner, NC 27529
(919) 395-4443

Inspected 11/14/2023
By: Angela Harrison, Drug Regulatory Specialist

Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services
Food and Drug Protection Division

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Director

Inspection Report

Pharmaceutical Trade Services Inc.
d/b/a Durbin USA, d/b/a Uniphar Clinical, d/b/a Uniphar
5100 Jones Sausage Road, Suite 140
Garner, NC 27529
(919) 395-4443

Inspected 11/14/2023
By: Angela Harrison

History of Business

Pharmaceutical Trade Services Inc., d/b/a Durbin USA, d/b/a Uniphar Clinical, d/b/a Uniphar is part of the Uniphar Group, a global life science and pharmaceutical distribution company. Pharmaceutical Trade Services Inc. has its principal place of business at 5820 Gulf Tech Drive, Ocean Springs, MS and is opening a new wholesale drug distribution facility at this address. The firm is affiliated with Uniphar Logistics USA, LLC located in Garner, NC under the parent company Uniphar plc located in Dublin, Ireland. The firm was licensed by NCDA&CS as a Wholesale Prescription Drug Distributor in November 2023.

Corporate Address

Pharmaceutical Trade Services Inc.
5820 Gulf Tech Drive
Ocean Springs, MS 39564

Corporate Officers

Dan Piggot	President
Melissa McLaughlin	Senior Vice President

Person(s) Interviewed and Individual Responsibilities

Credentials were presented and a Notice of Inspection issued to Mr. Erin Driggers, Head of Quality-US. Mr. Driggers, Mr. Bob Albanese, President, Uniphar Clinical, Mr. Mike Bernstein, Vice President, Uniphar Clinical, Mr. Rick Hughes, Managing Director, and Mr. Brian Pitchford, Operations Manager, accompanied me throughout the visual inspection of the facility and responded to all questions concerning the planned operation. Corporate policies and procedures and temperature records of the warehouse area were provided for review.

Background

This visit was the initial inspection of this facility following receipt of an application on 10/26/2023 for licensure as a Wholesale Prescription Drug Distributor. The purpose of this inspection was to verify compliance with NCGS §106 Article 12A prior to approval and release of the license.

Uniphar Logistics USA, LLC located in Suite 130, is contained within the same space, and maintains an active Third Party Logistics license #094-1713 in good standing with NCDA&CS.

Operations

Pharmaceutical Trade Services Inc. is part of the Uniphar Group, a global life sciences and pharmaceutical distribution company based in Dublin, Ireland. The facility in Garner is a new US location and will focus on providing an Expanded Access Program (EAP) to give patients with high unmet medical needs access to therapies that are not yet commercially available or approved in their country. The firm will provide services for primary solid dose packaging and labeling, as well as secondary packaging and labeling in support of masked clinical trials.

This facility is a new construction and contains a total of 65,000 ft.^{2} of space for administrative use, packaging, and storage. Access into and within the building will be limited to employees and escorted visitors and controlled by a digital card-key system; the entire facility is protected by a security system that includes intrusion alarms, glass break sensors, and surveillance cameras inside and outside. A limited-access storage vault of approximately 360 ft.2 is available for future storage of controlled substances; until this facility receives DEA approval, this area is being used for the segregated storage of outdated, damaged, or suspect products.

Temperature and relative humidity in all storage areas is controlled and continuously monitored by an environmental monitoring system, with designated personnel notified of excursions outside established ranges. A 500kw generator is available to support designated systems in the event of a loss of power. Rack storage is available for 3,000 pallets and shelf space is available for single-item bin storage at controlled-room temperature; storage space for cold-chain items with temperatures controlled at 2-8° C and cryogenic items was scheduled for installation shortly after the time of this inspection.

Corporate written procedures are established that address all areas of operations, including those required by NCGS §106 Article 12A. Inventory counts and discrepancy reconciliation, product rotation, and product recalls at the facility are defined in these procedures but may be at the direction of the client. The warehouse management system controls the movement of all products and maintains inventory count, location, and expiration dates of the products. Incoming drug products will be inspected for expiration dates, damages, and any other unusual appearances and entered into the system. The system is also responsible for the product hold process, restricting access to storage locations; these products may also

be identified by a label placed on the pallet and can be physically segregated and stored in a designated limited-access secure area in the warehouse.

Observations

There were no significant objectionable conditions noted during this inspection, and the Wholesale Prescription Drug Distributor license is approved.

Compliance

A limited inspection of operations at this facility will be conducted within 4-6 months.

Attachments

Notice of Inspection

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Nippon Express U.S.A., Inc.

Physical Address: 2900 Genesis Way, Suite 400

City: Grapevine State: TX Zip: 76051

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: 469-224-9000 Website: https://nipponexpressusa.com

Name of Designated Representative (DR): ~~Harry V. Barogh~~ Felipe Salinas

Licensing Company Email: HARRY.BAROGH@NIPPONEXPRESS.COM DR Email: HARRY.BAROGH@NIPPONEXPRESS.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers		☑ Others: Third Party Logistics Provider

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - This facility does not handle or distribute pharmaceutical products; only medical devices.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Nippon Express Co., LTD

Corporation/Organization Name: Nippon Express U.S.A., Inc.

Mailing Address: 2900 Genesis Way, Suite 400

City: Grapevine State: TX Zip: 76051

Telephone: 469-224-9000 Email: HARRY.BAROGH@NIPPONEXPRESS.COM

Contact Person Name: Harry V. Barogh

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
N/A 1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment A	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment B	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment C		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment A	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment D	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment E	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment F	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. See Attachment G		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. See Attachment H		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nippon Express U.S.A., Inc.

Facility Name

Harry V. Barogh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/16/2023

Date

Board Use Only	Date Received: 8/24/23	Amount: 1000-CK=30011275

Attachment A

Personnel Information

Nippon Express U.S.A., Inc. is wholly-owned by its parent company, Nippon Express Co., LTD. No individual holds any ownership interest in the company.

Top Corporate Officers:

Toshiya Abe
President and Chief Executive Officer

Takahiro Yamaguchi
Treasurer, Vice President and G.M. (FAD)

Roland Rock
Vice President (Midwest Region, CBO)

Bradley Hanna
Vice President, General Counsel and Secretary

Designated Representative:

Harry V. Barogh
Assistant General Manager

Attachment B

New York Certificate of Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	NIPPON EXPRESS U.S.A., INC.
DOS ID Number:	149604
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	07/31/1962
Effective Date:	09/29/2022
Statement Status:	CURRENT
Statement Due Date:	07/31/2024

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on May 24, 2024 at 11:16 A.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100005793637 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

NIPPON EXPRESS USA INC
2900 GENESIS AVE STE 400
GRAPEVINE TX 76051

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

NIPPON EXPRESS USA INC

2900 GENESIS AVE STE 400
GRAPEVINE, TX 76051

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE DISTRIBUTOR

License # 1002793
Expires: March 1, 2025

NON-TRANSFERABLE

Commissioner

513011

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/05/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): 800-363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Nippon Express USA, Inc. 800 North IL Route 83 Wood Dale IL 60191 USA	INSURER A: Sompo America Insurance Company	11126
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570107496557 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			AGL30029550401	01/01/2024	01/01/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			AAL30029537501	01/01/2024	01/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE / OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) Y/N N/A						E.L. EACH ACCIDENT	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	
A	Warehouse Legal Liability			HPR57000A0	01/01/2024	01/01/2025	Limit Deductible	$1,000,000 $10,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: Location/Site: 2900 Genesis Way, Ste 400 Grapevine, TX 76051;

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno NV 89521 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570107496557

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Attachment H

Surety Bond / Equivalent Means of Security

MUFG

MUFG Bank, Ltd.
New York Branch

APPLICATION FOR **AMENDMENT** OF **STANDBY** LETTER OF CREDIT

Date: 1/4/2023
Fax: _____
Ref. No.: _____

Office: MUFG Bank, Ltd., New York Branch

Attn: TSO/Standby LC Section

FOR BANK USE ONLY IRREVOCABLE CREDIT NO.		
MGR	**LAD**	**A/O**

L/C No. S533638N

For (US$) 25,000.00

Dated 03/29/2022

For Account of Nippon Express USA, Inc.

Please amend the above irrevocable Standby Letter of Credit by (●) Airmail ( ) Cable as follows:

NEW TERMS:	PREVIOUS TERMS:
EFFECTIVE DATE 01/04/2023 The Credit amount [✓] Increased [ ] decreased (please select one) By: 75,000.00 To: 100,000.00 Expiration Date is extended to: _____ Other: APPLICANT'S EMAIL: Kenny.Hughes@nipponexpress.com BENEFICIARY'S EMAIL: msedar@pharmacy.ny.gov	Credit amount: 25,000.00 Expiration date: 03/29/2023 Other:

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

SIGNATURE VERIFICATION [ ]

VERY TRULY YOURS,

Stefan Cajan

(AUTHORIZED SIGNATURE)

THIS AMENDMENT WILL BE SUBJECT TO (PLEASE SELECT APPLICABLE RULE)

(●) **UCP (2007 REVISION, ICC PUBLICATION NO. 600)**
( ) **ISP98 (ICC PUBLICATION NO. 590 INTERNATIONAL STANDBY PRACTICES)**

FOR BANK USE ONLY

C/A # _____ Purpose _____ Approval # _____ Evergreen Y/N _____

G/L Category _____ Facility Code _____ Guaranteed Y/N _____ Class Code _____

Grade Date _____ Review Date _____ Cost Center _____

OTHER:

BE MADE TO THE BOARD BY WIRE TRANSFER, TO THE BOARD'S ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, WITHIN THREE BUSINESS DAYS (AS HEREIN DEFINED) AFTER OUR RECEIPT OF A COMPLYING PRESENTATION. "BUSINESS DAY" MEANS ANY DAY OTHER THAN A SATURDAY, A SUNDAY OR ANY OTHER DAY COMMERCIAL BANKS IN THE NEW YORK CITY, NEW YORK, ARE AUTHORIZED OR REQUIRED TO BE CLOSED, AND A DAY ON WHICH PAYMENTS CAN BE EFFECTED ON THE FEDWIRE SYSTEM.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL GIVE THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND UPON FURTHER INSTRUCTIONS FROM THE BENEFICIARY, WE SHALL EITHER HOLD ANY DOCUMENTS AT THE BENEFICIARY'S DISPOSAL OR RETURN THE SAME TO THE BENEFICIARY.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT, WHICH MUST BE TIMELY MADE IN ACCORDANCE WITH THE TERMS OF THIS LETTER OF CREDIT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED .

11. THIS CREDIT WILL BE CANCELLED IN WHOLE ONLY UPON RECEIPT BY US OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD, ACCOMPANIED BY THE ORIGINAL LETTER OF CREDIT AND ALL AMENDMENTS, IF ANY.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED OR ASSIGNED, EITHER IN WHOLE OR IN PART.

14. EXCEPT SO FAR AS OTHERWISE EXPRESSLY STATED HEREIN, THIS LETTER OF CREDIT SHALL BE GOVERNED BY THE INTERNATIONAL STANDBY PRACTICES 1998, INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 590 ("ISP98"). THIS CREDIT SHALL BE DEEMED A CONTRACT MADE UNDER THE LAWS OF STATE OF NEW YORK, AND ANY ACTION RELATED TO THIS CREDIT SHALL BE FILED IN THE STATE OF NEVADA AND SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE NEW YORK. IN THE EVENT OF ANY CONFLICT, BETWEEN ISP98 AND THE LAWS OF THE STATE OF NEW YORK, THE LAWS OF THE STATE OF NEW YORK WILL CONTROL.

15. THIS STANDBY LETTER OF CREDIT EXPIRES ON MARCH 29, 2023. HOWEVER, IT IS A CONDITION OF THIS LETTER OF CREDIT THAT IT IS DEEMED TO BE AUTOMATICALLY EXTENDED WITHOUT AMENDMENT FOR ONE YEAR PERIOD (S) FROM THE CURRENT EXPIRATION DATE HEREOF, OR ANY FUTURE EXPIRATION DATE, UNLESS AT LEAST SIXTY (60) DAYS PRIOR TO ANY EXPIRATION DATE, WE NOTIFY YOU IN WRITING BY COURIER MAIL SERVICE TO THE BENEFICIARY'S ADDRESS STATED ABOVE

MUFG Bank, Ltd.

New York Branch
1251 Avenue of the Americas
New York, NY 10020
Tel: 201-413-8044
Fax: 201-521-2312
SWIFT: BOTKUS33XXX

Irrevocable
Standby Letter of Credit No.: S533638N

DATE: MARCH 29, 2022

NAME OF APPLICANT/LICENSEE: NIPPON EXPRESS USA, INC.
ADDRESS: 1901 W PACIFIC HIGHWAY
CITY: LONG BEACH
STATE: CALIFORNIA
ZIP: 90810
ATTN: KENNY HUGHES

TO BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF NIPPON EXPRESS USA, INC. , WE, MUFG BANK, LTD., NEW YORK BRANCH, HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT NO. S533638N(CREDIT) IN THE PRINCIPAL SUM OF U.S.$25,000.00 (UNITED STATES DOLLARS TWENTY FIVE THOUSAND AND 00/100).

2. WE HAVE BEEN INFORMED BY THE APPLICANT THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. WE HAVE BEEN INFORMED BY THE APPLICANT THAT THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS ABOVE.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY REGISTERED MAIL, RETURN RECEIPT REQUESTED.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT, PAYMENT SHALL

(OR AT SUCH OTHER ADDRESS AS MAY BE SPECIFIED FROM TIME TO TIME IN WRITING BY BENEFICIARY TO MUFG BANK, LTD., NEW YORK BRANCH) THAT WE ELECT NOT TO CONSIDER THIS LETTER OF CREDIT EXTENDED FOR ANY SUCH ADDITIONAL PERIOD.

WE HEREBY ENGAGE WITH YOU THAT ALL DOCUMENTS PRESENTED IN COMPLIANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT WILL BE DULY HONORED IF PRESENTED FOR PAYMENT AT OUR COUNTERS SPECIFIED ABOVE ON OR BEFORE THE EXPIRY DATE.

THEREFORE MUFG BANK, LTD., NEW YORK BRANCH HAS EXECUTED THIS IRREVOCABLE STANDBY LETTER OF CREDIT AS OF THE 29TH DAY OF MARCH , 2022

MUFG BANK, LTD., NEW YORK BRANCH

AUTHORIZED SIGNATORY

NAME: Ruth Dioquino
TITLE: Vice President

Attachment E

Medical Devices, Equipment and Gases Administrator Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Nippon Express U.S.A., Inc. MDEG License # (if applicable): N/A

Physical Address: 2900 Genesis Way, Suite 400

City: Grapevine State: TX Zip: 76051

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 469-224-9000 Website: https://nipponexpressusa.com

Licensing Company Email: felipe.salinas@nipponexpress.com

Section 2: Personal Information

First: Felipe Middle: N/A Last: Salinas

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 2900 Genesis Way, Suite 400

City: Grapevine State: TX Zip: 76051

Telephone: [redacted] Email: felipe.salinas@nipponexpress.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Winfree Academy Charter Schools		08/97 - 06/03	
Address	City	State	Zip
3110 Skyway Circle S	Irving	TX	75038
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2023 - Present	[redacted]	Coppell	TX	75019
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Nippon Express U.S.A., Inc.			6/21 - Present	
Business Address		**City**	**State**	**Zip**
2900 Genesis Way, Suite 400		Grapevine	TX	76051
Phone	**Title**		**Number of Employed Hours**	
469-224-9000	Assistant Operations Manager, Distribution Department		40 hours/week	
Description of Duties	Manages 3PL Distribution, handles the flow of goods from receipt, shipping and inventory control			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Felipe Salinas, **certify that as the MDEG Administrator for**

Nippon Express U.S.A., Inc.,

that I (initial that you have read and meet the following requirements):

1. FS Have a high school diploma or its equivalent;
2. FS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. FS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. FS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Felipe Salinas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only	Date Received:

Attachment C

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nippon Express U.S.A., Inc.
Pharmacy/Wholesaler License # (if applicable): Pending
Physical Address: 2900 Genesis Way, Suite 400
City: Grapevine State: TX Zip: 76051
Mailing Address (if different from physical address): Same as physical address.
City: State: Zip:
Telephone: 469-224-9000 Website: https://nipponexpressusa.com
Licensing Company Email: felipe.salinas@nipponexpress.com

Section 2: Personal Information

First: Felipe Middle: N/A Last: Salinas
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: 2900 Genesis Way, Suite 400
City: Grapevine State: TX Zip: 76051
Telephone: [redacted] Email: felipe.salinas@nipponexpress.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WinFree Academy Charter Schools		08/97 - 06/03	
Address	**City**	**State**	**Zip**
3110 Skyway Circle S	Irving	TX	75038
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2023 Present	[redacted]	Coppell	TX	75019
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Nippon Express U.S.A., Inc.			6/21 - Present	
Business Address		**City**	**State**	**Zip**
2900 Genesis Way, Suite 400		Grapevine	TX	76051
Phone	**Title**		**Number of Employed Hours**	
469-224-9000	Assistant Operations Manager, Distribution Department		40 hours/week	
Description of Duties	Manages 3PL Distribution, handles the Flow of goods from receipt, shipping and inventory control.			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Felipe Salinas, **certify that as the designated representative for**

Nippon Express U.S.A., Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. F.S I am at least 21 years of age;
3. F.S I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. F.S I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. F.S I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. F.S I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. F.S I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Felipe Salinas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/8/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Felipe Salinas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-12-2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Felipe Salinas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-12-2024

Date

Subscribed and Sworn to before me this 12th day of March.

Notary Public Signature

WADE LEO BELLARD
Notary ID # 13299205-6
My Commission Expires
03-23-2025

(Seal)

NIPPON EXPRESS GRAPEVINE HEADCOUND		
NO	NAME	TITLE
1	FELIPE SALINAS	OP. ASST. MGR
2	MOISES GRCIA	TEAM LEAD
3	RAUL GONZALEZ	TEAM LEAD
4	INGRID CASTILLO	CSR/QC
5	ANA MEDINA	CSR/QC
6	VLADIMIR GUERRERO	DISTRIBUTION CHECKER
7	HUGO VICENTE	DISTRIBUTION CHECKER

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY
■ Ownership Change (Provide current license number if making changes:) OUT 00011
☐ 503a OR ■ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
■ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: F.H. Investments Inc. d/b/a Asteria Health

Physical Address: 7004 Champion Blvd. Suite 100

City: Birmingham State: AL Zip Code: 35242

Telephone: 205-995-0505 Fax: 205-995-0507

Toll Free Number: 855-771-0505 (Required per NAC 639.708)

E-mail: licensing@biote.com Website: asteriahealth.com

Supervising Pharmacist: Christopher Musser Nevada License #: 20144

SERVICES PROVIDED

Yes/No

☐ ☑ Parenteral
☑ ☐ Sterile Compounding
☑ ☐ Non Sterile Compounding
☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500-check 0219647Z

FEI Number (From FDA application): 27-2844223

Please provide the name of the facility as registered with the FDA and the registration number:
F.H. Investments, Inc. d/b/a Asteria Health FDA Registration no. 3010348724

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Asteria Health

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Christopher Musser Nevada License Number: 20144

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ■

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Mary Elizabeth Conlon

Print Name of Authorized Person

2.15.2024

Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Alabama

Parent Company if any: Biote Medical LLC

Address: 7004 Champion Blvd., Suite 100

City: Birmingham State: AL Zip: 35242

Telephone: 205-995-0505 Fax: 205-995-0507

Contact Person: Christopher Musser

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) The applicant entity, F.H. Investments, Inc. d/b/a Asteria Health, is 100% owned by Biote Medical LLC. 1875 W. Walnut Hill Ln, Suite 100, Irving, TX 75038
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. wholly owned by Biote Medical LLC

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? Closing is set for on or about March 1, 2024

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Wes Allen
Secretary of State

P.O. Box 5616
Montgomery, AL 36103-5616

STATE OF ALABAMA

I, Wes Allen, Secretary of State of Alabama, having custody of the Great and Principal Seal of said State, do hereby certify that

the entity records on file in this office disclose that F.H. Investments, Inc. was formed in Shelby County on May 13, 2010. The Alabama Entity Identification number for this entity is 000-264-200. I further certify that the records do not disclose that said entity has been dissolved, cancelled or terminated.

In Testimony Whereof, I have hereunto set my hand and affixed the Great Seal of the State, at the Capitol, in the city of Montgomery, on this day.

02/12/2024

Date

Wes Allen **Secretary of State**

20240212000013510

Alabama State Board of Pharmacy

2024

This is to certify:

F H INVESTMENTS, INC DBA ASTERIA HEALTH
7004 CHAMPION BLVD
SUITE 100
BIRMINGHAM, AL 35242

Permit Number:

195381

Is Duly Licensed as a:

503-B Outsourcing Facility

Specialty Services:

Supervising Pharmacist

WILLIAM EARL FIXLER

14696

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2024

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

Donna C Yeadman
EXECUTIVE SECRETARY

Alabama State Board of Pharmacy

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

2024

Controlled Substance Number:	Business Activity:	Schedules:
195381	503-B Outsourcing Facility	III

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:
(1) Has furnished false or fraudulent material information in any application filed under this Act,
(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or
(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances
(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: 01/01/2023

Expiration Date: 12/31/2024

F H INVESTMENTS, INC DBA ASTERIA HEALTH
7004 CHAMPION BLVD
SUITE 100
BIRMINGHAM, AL 35242

CERTIFICATE MUST BE PROMINENTLY DISPLAYED AT ALL TIMES
THIS REGISTRATION IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RF0532362	09-30-2024	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,4,5	MANUFACTURER	08-22-2023

FH INVESTMENTS INC
ASTERIA HEALTH
7004 CHAMPION BLVD
SUITE 100
BIRMINGHAM, AL 35242

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RF0532362	09-30-2024	$3699

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FH INVESTMENTS INC
ASTERIA HEALTH
7004 CHAMPION BLVD
SUITE 100
BIRMINGHAM, AL 35242

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

MWD INSPECTION

☐ Not Licensed

AL License Number	DEA Number	Status
195381	RF0532362	Closed - Compliant
Contact1	**Contact1 Email**	**Contact2**
Bill Fixler		Bill Fixler
Contact2 Email	**Inspection Type**	**Inspection Date**
	Routine	09/25/2023

Inspector Name

Mdelk

Type Operations

☑ M/W/D (Prescription Drugs or Controlled Substances
☐ M/W/D (Precursor Chemicals)
☐ M/W/D (Veterinarian)
☐ (Repackager) 34-23-32 (b) requires pharmacist for repackaging operations.

☐ Case nber

ADDRESS INFORMATION

Address 1 : 7004 CHAMPION BLVD
Address 2 : SUITE 100
City : BIRMINGHAM
State / Zip : AL 35242

STORAGE CONDITIONS

Facility must have proper lighting.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
The storage area must be kept free from infestation by insects, rodents, birds or vermin of any kind and must be maintained in a clean and orderly manner.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
All drugs or medicines must be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such drugs or medicines or with the requirements in the current edition of an official compendium. If no storage requirements are established for a drug or medicine they may held at "controlled" room temperature as defined in an official compendium to help ensure the identity, strength, quality, and purity of the same are not adversely affected.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
Must have appropriate manual, electromechanical, or electronic temperature and humidly recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
A separate quarantine storage section must be provided for drugs or medicines that are deteriorated, outdated, misbranded, or otherwise adulterated, or that are in immediate or sealed secondary containers that have been opened.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
Drugs shipments must be visually examined for identity and to prevent the acceptance or distribution of contaminated or damaged products.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)

FACILITIES

Must be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

Buildings must meet all applicable federal, state and local standards. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

A facility may not be located in a residence. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

SECURITY

Facility secure from unauthorized entry. ☑ Yes ☐ No ☐ N/A
Key pad locked entry door.
680-X-2-.23 (2c)

Facility must be equipped with an alarm system to detect entry after hours. ☑ Yes ☐ No ☐ N/A
CSV ALARM
680-X-2-.23 (2c)

Must ensure access from outside their premise is reduced to a minimum and well controlled. This includes but not limited to, the installation of adequate lighting at the outside perimeter. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Internal security policies to provide reasonable protection against theft by personnel. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Policies for protection against computer theft and crimes. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Entry to areas where drugs are held shall be limited to authorized personnel. ☑ Yes ☐ No ☐ N/A
Secured at all times.
680-X-2-.23 (2c)

RECORD KEEPING REQUIREMENTS

Drug Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. Shall consist of the following:
1. The source of all drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

2. The identity and quantity of the drugs received and distributed or disposed of. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

3. The dates or receipt and distribution or disposition of the drugs. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

Inventories and records must be kept 2 years following disposition of the drugs, for inspection and photocopying. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

All records described in this rule, that are kept on site or that can be immediately retrieved by computer or other electronic means shall be readily available for inspection during the retention period. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by authorized personnel.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (2e1)

All charge back transactions must be maintained separately from al other records.

☑ Yes ☐ No ☐ N/A

Reviewed multiple physicians orders.

680-X-2-.23 (2e1)

Copies of records and reports required by DEA concerning the increases in purchases or high volumes purchased by pharmacies, shell be forwarded to the Board of Pharmacy.

☑ Yes ☐ No ☐ N/A

Last DEA INSPECTION 9-22-21.

680-X-2-.23 (2e1)

WRITTEN POLICIES AND PROCEDURES

A procedure to ensure that wholesale drug distributors prepares for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or any other situation of local, state, or nation emergency.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.i)

A written procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs and shall be maintained for two (2) years.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.ii)

A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation if temporary and appropriate.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iii)

A procedure to be followed for handling recalls and withdrawals of drugs which shall be adequate to deal with recalls and withdrawals due to:
1.Any action initiated at the request of the FDA or other Federal, State or Municipal law enforcement or other governmental agency including the Alabama State Board of Pharmacy.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

3. Any action undertaken to promote public health and safety by placing existing merchandise with an improved product or new package design.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

CHEMICAL PERMIT HOLDERS

A licensee shall make an accurate and legible record of any transaction of listed precursor chemicals and maintain such record together with the following records for a period of at least two (2) years:
1. Inventory on hand

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

2. Purchase receipts.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

3. Manufacturing records including the date and quantity of any listed precursor chemicals manufactured, the quantity of listed precursor chemicals used in the manufacturing any other substance or product, and the inventory on hand of listed precursor chemicals after the manufacturing of any substance or product

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

4. Copies of the Board of Pharmacy licenses or permits.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

5. Records of substance disposal.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

COMMENTS

503B SELL MANUFACTURING AND SELLS ESTRADIOL PELLETS AND TESTOSTERONE TO PHYSICIANS OFFICES. WHSE SPECTRUM, VIEWED CS INVENTORY 1-15-2023. UNIT/GRAMS. DEA RF0532362. FEI 3010348724. NABP ACCREDITATION.2023. RPH BILL FIXLER 14696 RPH ROBIN FIXLER 14698.

F.H. Investments Inc. d/b/a Asteria FDA Disclosure

Asteria has been the subject of one FDA inspection from June 12, 2018 to July 10, 2018. At the end of the inspection, FDA issued a Form 483 with five observations. FDA issued an establishment inspection report ("EIR") closing out this inspection on November 7, 2021. Attached is a copy of the Form 483 and EIR.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

September 10, 2021

William E. Fixler
Co-Owner & Pharmacist in Charge
FH Investments Inc. dba Asteria Health
7004 Champion Boulevard, Suite 100
Birmingham, AL 35242

Mr. Fixler:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, FH Investments Inc. dba Asteria Health, located at 7004 Champion Boulevard, Suite 100, Birmingham, AL 35242, from June 12, 2018, through July 10, 2018, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact please contact Shawn Larson – Compliance Officer at 214-253-5216.

Sincerely,

CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

Separate Enclosure: EIR

Cc: Alabama State Board of Pharmacy (cover letter only)
Donna Yeatman, RPh - Executive Secretary
111 Village Street
Birmingham, AL 35242

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
One Main Place, 1201 Main Street, STE 7200
Dallas, TX 75202
www.fda.gov

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SUMMARY

This surveillance cGMP inspection of an outsourcing facility was conducted in accordance with a CDER Assignment issued on 1/30/2018. The MARCS Operation ID is 89829. This was the initial inspection of this facility.

The current inspection resulted in the issuance of a 5-item FDA 483 with the following observations:

1) Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process;
2) Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity;
3) Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product;
4) There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed; and
5) Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

Additionally, one verbal observation was discussed with management regarding the environmental controls necessary for the manufacture of terminally sterilized drug products. They committed to responding to the FDA 483 within 15 business days. No samples were collected and no refusals were encountered.

FDA correspondence should be addressed to:

William (Bill) E. Fixler, Co-Owner & Pharmacist in Charge
FH Investments Inc. dba Asteria Health
7004 Champion Boulevard, Suite 100
Birmingham, AL 35242

ADMINISTRATIVE DATA

Firm Name:	FH Investments Inc. dba Asteria Health
Firm Address:	7004 Champion Boulevard, Suite 100 Birmingham, AL 35242
Phone:	(205) 995-0505
Fax:	(205) 995-0507
Website:	www.asteriahealth.com
Dates of Inspection:	6/12-15, 18-20/2018, 7/2/2018, & 7/10/2018
Days at Firm:	9 days
Participants:	Samantha J. Bradley, Certified Drug Investigator Dorcas Ann Taylor, CDER Compliance Officer Todd Brooks, Drug Inspector, AL BOP

We arrived on 6/12/2018 and were introduced to William (Bill) E. Fixler, Co-Owner & Pharmacist in Charge (PIC), who identified himself as the most responsible individual at the site. We presented our credentials and issued an FDA 482, Notice of Inspection, to him. Mr. Fixler accepted the FDA 483, Inspectional Observations, on 7/10/2018.

Dorcas Ann Taylor, CDER CO, participated in the inspection on 6/12-15, 18-20/2018. Mr. Todd Brooks, Drug Inspector for the Alabama Board of Pharmacy (AL BOP) was present on 6/14/18, 7/2/18, and 7/10/18 under his own authority.

This report was written by Investigator Bradley.

HISTORY

FH Investments was incorporated as a LLC (limited liability corporation) in the state of Alabama in 2017. It is privately owned by three co-owners. They originally registered with the FDA as an outsourcing facility on 5/18/2017 and most recently registered on 1/6/2018.

Asteria operates Monday through Friday from 9:00 am to 5:00 pm. They have 6 full-time employees, as shown in their organizational chart (**exhibit 1**). Asteria produces hormone pellets intended for sub-cutaneous implantation. All compounded products are sold to physician's clinics per order (not prescription) and are intended for administration by medical personnel.

Asteria intends to move to a new location once they have completed designing and building a new facility. The new building will include facilities so that laboratory testing can be performed in-house. There was no anticipated time-frame for this at the time of this inspection. FH Investments also owns Asteria Specialty Pharmacy, which is a 503A pharmacy which has not yet begun operations. The facility is currently under construction in Birmingham, AL.

FDA correspondence should be addressed to:

William (Bill) E. Fixler, Co-Owner & Pharmacist in Charge
FH Investments Inc. dba Asteria Health
7004 Champion Boulevard, Suite 100
Birmingham, AL 35242

INTERSTATE COMMERCE AND JURISDICTION

The firm is registered with the US FDA as an outsourcing facility under section 503B of the Act. They manufacture sterile drug products which are shipped into interstate commerce in the US market for use. As such, the firm is subject to the adulteration provisions of section 501(a)(2)(b) of the Act, which requires all drugs to be manufactured in conformance with current Good Manufacturing Practices.

Asteria has been manufacturing products since 02/2018 and distributing products since 03/2018. They have made the following products:

Product Number	Product Description	Dosage Form	Active Ingredient
S-E006	Estradiol 6mg Pellet	Pellet, Implantable	Estradiol
S-E010	Estradiol 10mg Pellet	Pellet, Implantable	Estradiol
S-E012.5	Estradiol 12.5mg Pellet	Pellet, Implantable	Estradiol
S-E015	Estradiol 15mg Pellet	Pellet, Implantable	Estradiol
S-E018	Estradiol 18mg Pellet	Pellet, Implantable	Estradiol
S-E020	Estradiol 20mg Pellet	Pellet, Implantable	Estradiol
S-E025	Estradiol 25mg Pellet	Pellet, Implantable	Estradiol
S-T012.5	Testosterone 12.5 mg Pellet	Pellet, Implantable	Testosterone
S-T025	Testosterone 25 mg Pellet	Pellet, Implantable	Testosterone
S-T050	Testosterone 50 mg Pellet	Pellet, Implantable	Testosterone
S-T087.5	Testosterone 87.5 mg Pellet	Pellet, Implantable	Testosterone
S-T100	Testosterone 100 mg Pellet	Pellet, Implantable	Testosterone
S-T200	Testosterone 200 mg Pellet	Pellet, Implantable	Testosterone

All products are terminally sterilized and intended for subdermal implantation. Products are currently distributed into Alabama (about 40%) and Mississippi (about 60%). Additional strengths advertised as available for production, but not yet manufactured, include an Estradiol 37.5 mg Pellet and Testosterone 37.5 mg Pellet. Asteria also sells commercially-available Trocar Kits per physician request. Trocar kits are used for the implantation of pellets by medical staff. Asteria does not handle cytotoxic or beta-lactam products. No products are lyophilized.

Hormone pellets are made using three major parts: starting material trituration, hormone blend mix, and pelleting/vialling (finished product). This process results in the generation of up to three lot numbers per finished product. The same blend may be used to make multiple finished product batches. Trituration of the starting material began in late March 2018, so not all released products include an internally generated starting material batch number. The following is a summary of all released hormone pellet batches:

Starting Material	Material Lot #		Intermediate Blend	Blend Lot #		Finished Product	Product Lot #
n/a	n/a	--	Testosterone Powder Blend	02022018@1	→	Testosterone 100 mg Pellet	02022018@2
					→	Testosterone 200 mg Pellet	02052018@3
n/a	n/a	--	Testosterone Powder Blend	02052018@1	→	Testosterone 12.5 mg Pellet	02062018@2
					→	Testosterone 25 mg Pellet	02062018@3
					→	Testosterone 50 mg Pellet	02062018@1
n/a	n/a	--	Testosterone Powder Blend	02072018@1	→	Testosterone 87.5 mg Pellet	02072018@2
					→	Estradiol 12.5 mg Pellet	03062018@1
n/a	n/a	--	Estradiol Powder Blend	03012018@2	→	Estradiol 20 mg Pellet	03022018@2
					→	Estradiol 25 mg Pellet	03022018@3

Stearic Acid Triturated	03232018@1	→ Testosterone Powder Blend	03232018@2	→ Testosterone 200 mg Pellet	03232018@4
				→ Estradiol 6 mg Pellet	05222018@3
Stearic Acid Triturated	05222018@1	→ Estradiol Powder Blend	05222018@2	→ Estradiol 10 mg Pellet	05232018@1
				→ Estradiol 15 mg Pellet	05242018@1
				→ Estradiol 18 mg Pellet	05282018@1

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

We were provided with an organizational chart for Asteria Health (**exhibit 1**).

William (Bill) E. Fixler, Co-Owner & Pharmacist in Charge (PIC), is the most responsible individual at Asteria Health. He is responsible for product formulation, compounding, production, and packaging activities. He is ultimately responsible for the overall compliance of Asteria Health. Mr. Fixler was present each day of the inspection and provided information specific to the operations in which he is involved. All references to Mr. Fixler within this report are in reference to Mr. Bill Fixler unless otherwise noted.

Wayne Fixler, Co-Owner & Compliance Manager, is responsible for overseeing compliance activities for Asteria Health including activities such as registration, product reporting, and licensing. He provided information relating to sales, product reporting, and registration during the inspection.

Carla Kutz, Quality and Regulatory Affairs Manager, oversees the quality operations as Asteria Health. She has been working with Asteria Health since July 2017, but officially began in September 2017. She was previously the Director of Quality and Regulatory Affairs at DynaLabs, LLC. Ms. Kutz was our primary contact during the inspection and provided the majority of information contained within this report.

Larry D. Stephens, Pharmacist, has been with Asteria since 01/2018. He serves as one of the pharmacists responsible for compounding and packaging operations. He was not actively involved in the inspection. Jonathan (Jon) R. Morrow, Pharmacist, has been with Asteria since 01/2017. He has performed compounding and packaging operations during his employment, but is no longer as actively involved in 503B compounding activities. Mr. Morrow is working to assist with 503A facility design and will operate as the pharmacist in the 503A facility exclusively once it opens.

INSPECTIONAL COVERAGE

Asteria compounds implantable pellets under controlled conditions which are e-beam (electron beam) sterilized in their final product vial. This is the only process currently being performed.

Quality

The quality system at Asteria appeared to be in an overall state of control. Ms. Kutz is the head of the Quality Control Unit. No major concerns were noted with document control, approval and release activities and records, SOP review and approval, or employee training and records. One comment was discussed with Ms. Kutz regarding control over the green "Release" stickers used for raw material identification. She understood and corrected this concern during the inspection.

Complaints & Adverse Event Reporting

Asteria began selling their implantable drug product in 03/2018. They had not received any complaints at the time of this inspection. Their complaint handling procedure is attached as **exhibit 23**. No concerns were noted with complaint handling, but there are no instructions to review for and report Adverse Drug Events. See *Observation 5* for additional details.

Recall

Asteria has never performed a recall. Their recall SOP is attached as **exhibit 24**. I had no concerns with the procedure in place. Traceability exercises are performed twice per year, but were not reviewed during this inspection.

Facilities & Equipment

Asteria is located in a small business complex off of Highway 280. Their facility is designed with limited access areas using keycard entry and monitored with security cameras. Due to their handling of testosterone, a controlled substance, they also utilize restricted access material cages and safes. An overview of the facility is provided in **exhibit 3**. No concerns were noted with the facility conditions.

Production Facility Design

The areas in which production activities occur are certified as ISO 7 and ISO 8, but Asteria made it clear they are not claiming these conditions during production. They explained they are "as clean as can be" rooms. I discussed the expectation to produce products intended to be sterile in controlled environments, with a minimum cleanliness of ISO 8. See *Verbal Observation 1*.

There are no ISO 5 hoods or areas at Asteria. Products are handled and made within dust control hoods located within ISO 7 or ISO 8 rooms. All doors, including in material pass-throughs, are interlocked. No concerns were noted with the flow of personnel and materials.

Facility and Hood Certification

Production activities take place in Rooms 16, 17, 18, and 19. Personnel enter through the main ante room, Room 16, which is positive pressure and certified to ISO 8. Blends are prepared in a dust control hood in Room 17, which is negative pressure and certified to ISO 8. Pelleting and vialling are performed in a dust control hood in Room 19, which is negative pressure and certified to ISO 7. Entry into this room is through Room 18, which is positive pressure and certified to ISO 7.

Facility certification is performed by ENV Services, Inc. based out of Hatfield, PA 19440. The most recent two certifications were performed in June 2018 and December 2017. Services include air changes per hour, non-viable particle counts, HEPA leak testing, and pressurization. Additionally, they perform viable sampling in controlled rooms including bacterial and fungal surface and air samples.

Pressure Monitoring

Ms. Kutz explained that she recently implemented the printing and inclusion of pressure data within batch documentation for each product. I reviewed several of these during batch record review. I noted there are no explanations for discrepancies which occur, such as pressure loss. I discussed the records including notes to explain excursions and Ms. Kutz agreed to update their practices. Although I noted excursions occurring, based on the design of the compounding rooms, which have both positive and negative pressures, excursions are expected each time a door is opened between a room with opposite pressure settings. No extended excursions were noted during review.

Equipment Calibration and Certification

ENV Services performs calibrations for all equipment used by Asteria for environmental monitoring of their cleanrooms. This includes temperature, pressure, and relative humidity gauges. They also certify the dust control hoods used for product handling (AST001, AST002, and AST023). I had no concerns after reviewing the certification and calibration data.

I reviewed the equipment used during production of the products including balances, hoods, torque wrench, and calipers. This equipment was observed to be within calibration and routinely scheduled for calibration/maintenance, with the exception of the calipers. The calipers are used to measure pellet length during production.

Ms. Kutz explained the manufacturer does not recommend calibration or preventative maintenance. She stated the calipers are calibrated to 'zero' each day of use. I explained this equipment is being used to measure a critical quality attribute of the drug product and it requires calibration on some frequency. In response to our discussion, the calipers in use were sent to CALTECH located in Oxford, AL 36203, and were found to be In Tolerance for calibration parameters. I was provided with a copy of the certification. Ms. Kutz explained they also purchased a certified master gage block set for internal verifications and updated their SOP to require annual calibration. I had no additional concerns.

Disinfection of Production Areas

Asteria uses the following disinfectants and cleaners:

- TrueCare Biomedix Sterile IPA 70% Cleanroom Wipes (low shedding)
- Veltek Associates Inc. HYPO-CHLOR 0.52% Sterile Sodium Hypochlorite in USP Water for Injection

- Decon Labs CiDehol ST Sterile 70% IPA
- Veltek Associates, Inc. DECON-SPORE 200 Plus Sterile Peracetic Acid and Hydrogen Peroxide

Asteria has not performed disinfectant effectiveness testing, but Ms. Kutz stated she is in the process of developing the protocol for one. They are currently basing effectiveness on the organisms the manufacturers state are neutralized in combination with results from the EM program.

Facility cleaning is described in SOP NSC 04, Terminally Sterilized & Non-Sterile Compounding Cleaning and Restocking, Version 1, Effective 10/15/2017. Cleaning is performed each day of use, weekly (minimum when not in use), and monthly. The sporicide is used once per month. I discussed the frequency of sporicide use and explained they must ensure monthly is frequent enough based on their findings from their EM samples. Additionally, I discussed the lack of specific details within the cleaning SOP on how cleaning is being performed and critical elements, such as dwell time. Ms. Kutz committed to adding more detail to the SOP.

Equipment Cleaning

During review of the process for production of both hormone products, we determined several pieces of equipment are used for both. The cleaning process has not been validated to ensure the disinfectants and methods in use effectively remove residual hormone powder to prevent cross-contamination. See *Observation 3* for additional details.

Environmental Monitoring

Environmental monitoring (EM) in compounding areas is outlined in SOP CMP 09, Environmental Monitoring, Version 1, Effective 10/15/2017 (**exhibit 27**). Routine personnel monitoring is not performed; it is only performed during gowning qualification activities. Per this procedure, EM is performed from the dirtiest to cleanest rooms and monitoring is not required for hoods and rooms each day unless they are used. TDA and SDA media which have been growth promoted are used and all growth is submitted for full identification. Disinfectant neutralizers are present in both types of media. Although gravity plates, or passive air plates, are described in the procedure, they are not currently in use at Asteria.

The specific EM performed is described in SOP NSC 05, Terminally Sterilized & Non-Sterile Compounding Environmental Monitoring, Version 2, Effective 5/21/2018 (**exhibit 28**). Sampling locations are shown on the corresponding Form, NSC 05 Form 1 (**page 4**). EM is performed prior to operations each day of use in the pelleting room (Room 19). It is performed in the mixing room (Room 17) day of use or at least weekly. EM includes non-viable particles (NVP), viable air samples, and surface samples. One of the NVP samples is taken under dynamic conditions and the surface sample is taken on the work surface used during operations.

I discussed sampling only occurring before operations with management and explained they are missing the collection of significant data. Ms. Kutz explained they did not want the extremely fine powder to impact the NVP samples or have the non-sterile excipient and API add microbes to their EM data. I explained the sampling should represent the conditions to which the product is exposed. They understood and promised to begin monitoring after operations as well.

I reviewed the trending of the data which had been collected since 01/2018 (**exhibit 29**). For viable monitoring, a deviation relating to one of their contract labs prevented them from obtaining identification for each situation during which CFUs were found. Counts are routinely 0 CFU and have not been higher than 3 CFU for any viable air or surface sample. The data indicates a level of control, though "after production" samples have not yet been taken. NVPs were also reviewed and none were observed to be outside acceptable ranges for ISO 7 or ISO 8 conditions.

Based on Asteria not considering the rooms classified, they have not set alert and action levels for the EM findings. Per the procedure, the results are for information purposes only. I discussed establishing limits and having a system in place to address how they will handle any findings which exceed them.

Materials

SOP MSP 03, Material Supplier Approval, Version 1, effective 9/1/2017, defines the requirements for the approval of suppliers for any packaging, raw material, intermediate, finished product, processing aid, and disposable or reusable supplies or equipment. Each supplier is approved prior to Asteria accepting materials and may be approved via an on-site audit or questionnaire. The SOP defines the information which must be provided from each type of supplier to be considered for approval.

Quality reviews information from the audits or questionnaires to determine if they are acceptable. Single source or critical suppliers are audited at least every 2 years. I reviewed the approved supplier list and several supplier questionnaires and had no concerns.

Material Acceptance

The APIs and excipients received by Asteria are currently fully tested per USP while their supplier is being qualified. Once they have been qualified, Asteria will perform identity testing for each material received. They also require a COA (certificate of analysis) accompany materials prior to acceptance. Examples of COAs for the APIs and excipient are shown in **exhibit 25**. Materials are identified with a sticker indicating their release status (yellow for quarantine, green for released).

Containers and closures are purchased sterile. They are accepted after verifying the information provided on an accompanying COA or COC (certificate of compliance) along with a visual inspection. They are logged into inventory (PK Compounder) and physically identified with their status.

Production

Production activities are captured on batch records and PK Compounding records. Batch records are completed as a batch is produced over several days. PK records are generated afterwards based on the information captured within the batch records; they are used to track material inventory.

Gowning

All gowning components used in the production areas of Asteria are sterile. Additional safety equipment is used for the compounding performed in Room 19. This involves the use of a respirator, specifically, a 3M Versaflo Respirator. In full gowning with the respirator, no operator skin is exposed. The respirator cannot be sterilized. It is routinely cleaned using sterile 70% IPA and sterile 0.52% hypochlorite solution.

Production Technique

Pellets are completed in five parts: stearic acid trituration (since 03/2018), powder blending, pelleting, vialing, and labeling.

Stearic acid is triturated within the powder control hood in Room 17. This is done to obtain uniform particle size to assist with flowability of the final blend for pelleting. This activity is captured in the Triturated Stearic Acid Record, SAP v4, CR18-084, effective 4/15/2018. This powder is used for both testosterone and estradiol pellets.

Powder blending is also performed within the powder control hood in Room 17. The API, estradiol or testosterone, and triturated stearic acid are measured into a single-use polypropylene jar (usually 4 or 8 oz.). The jar is closed with a screw cap within the hood and then placed in the RAM (Resonant Acoustic Mixer) for blending. The RAM is located on a table in Room 17. Estradiol is captured on the Estradiol-Stearic Acid Powder Mix Record, EPM v4, CR18-083, effective 4/15/2018. Testosterone is captured on the Testosterone-Stearic Acid Powder Mix Record, TPM v4, CR18-082, effective 4/15/2018.

Pelleting is performed within the powder control hood in Room 19. The pellet press is located within the hood. Pellet dimensions are critical to the assay of each individual pellet. The dimensions are determined using information from each API COA and will change based on this information. The pellet press is manually set-up for each batch of product. Pellet die sets are dedicated for each API. Each die is identified with a different strength. During the initial set-up of the pellet press, pellet length and weight are checked against the specifications. Once set, the pellets are 100% weigh checked and only checked for length at the middle and end of each run.

Estradiol pelleting is captured on the Estradiol Pelleting Record, EDP v4, CR18-078, effective 4/15/2018. Testosterone pelleting is captured on the Testosterone Pelleting Record, TRP v4, CR18-079, effective 4/15/2018.

Hold Times

During production, the API powder blends are allowed to be used for about 6 months after they have been blended. I asked for a study which showed the blends do not physically separate and was informed this has not been performed. I expressed my concerns with the powder blends physically separating over the course of time and Ms. Kutz committed to re-blending the powder immediately before use for each batch of product.

Batch Record Review

During review of batch records, I discussed concerns with the documentation of activities. Specifically, during pelleting and vialing, it is not clear from batch documentation how much waste was generated during set-up activities compared to in-process waste. Although finished product and waste are tracked through identification of Jar 1 and Jar 2, these same jar numbers are used during pelleting and packaging operations, which make it difficult to follow. Additionally, there is a third jar in use during pelleting which is not appropriately documented. It is used to catch the pellets as they are ejected from the pellet press.

For weight and length checks, there are no specific instructions which state weight and length failures must be documented. It is not clear if the number of weight checks documented are the number of pellets produced or the number of pellets which passed. There is no differentiation between weight and length checks during set-up versus during production. There is no tracking of pellet failures or the reason for failure.

I explained it is critical that set-up and in-process waste be differentiated between to establish a "norm" and identify anomalies. It is also critical they identify and track any pellet failures once set-up has been completed to identify drift and anomalies. The total number of pellets made is unclear which means the significance of anomalies cannot be established. Management understood my concerns with the batch records.

Electron Beam Sterilization

Hormone pellets are terminally sterilized via a third party contractor using e-beam (electron beam). Asteria contracts with MediZap for the e-beam service. MediZap has developed a packaging system for pellets which is used in the e-beam process. MediZap contracts with Steri-Tek for the e-beam process. Steri-Tek contracts with Pacific Biolabs to perform testing associated with the validation of e-beam sterilization. In summary:

Company	Roles
MediZap 4010 Technology Way Unit A-C Carson City, NV 89706	• Contracted by Asteria Health • Coordinates e-beam sterilization with Steri-Tek • Established the packaging components and configuration for pellets

Steri-Tek 48225 Lakeview Blvd Fremont, CA 94538 (510) 933-9700 www.steri-tek.com	• Contracted by MediZap • Previously Nutek Corporation • Performed validation for hormone pellets per ISO 11137-2 using VD_{max}^{25}
Pacific BioLabs (PBL) 551 Linus Pauling Drive Hercules, CA 94547 (510) 964-9000 www.pacificbiolabs.com	• Contracted by Steri-Tek • Performs the following per ISO 11737: o Bioburden Analysis o Bacteriostasis/Fungiostasis o VD Max Dose Audit (Sterility Testing)

During review of the validation documentation, I noted it lacks the identification of critical process parameters and acceptance criteria. I also determined through conversation with Asteria management that they are not familiar enough with the process to identify significant steps and attributes which may impact the validation. Both of these deficiencies were discussed with management. More significant concerns were noted with the validation pertaining to the use of other company's compounded pellets and the methods used by PBL during testing. These are described in *Observation 1*.

Packaging & Labeling

Pellets are manually packaged into individual vials and then a micro-capper is used to apply the appropriate torque to each cap for each vial. Torque is verified during set-up using a calibrated torque wrench. This is performed within Room 19, under the same controls used for pelleting. Visual inspection of the pellets includes identifying any damage, breakage, powder, or debris.

Estradiol vialing is captured on the Estradiol Pellets – Vialing Record, EPV v2, CR18-080, effective 4/15/2018. Testosterone vialing is captured on the Testosterone Pellets – Vialing Record, TPV v2, CR18-081, effective 4/15/2018.

In-process products are labeled using PK printed labels. These labels are not retained in batch records. In-process products are normally identified with a single label (bulk are kept together) and their locations are tracked through various logbooks used in different storage areas. The logbooks were reviewed in several different locations and no concerns were noted.

Finished product labels are printed per templates and reconciled for each batch of product. Labeling for both product types is captured on the Labelling and Retain Record, V2, C18-066, effective 3/27/2018. Labels are reviewed for accuracy prior to application and after labeling is completed, as captured through the QA Review/Approval sections on the record. A label is attached to each batch record and each PK Software record.

Container Closure Integrity Testing

CCIT (container closure integrity testing) was originally performed as part of the stability study in 2017, though it was discontinued after several failures were identified by the third-party lab. See the summary of stability lots in the *Stability & Method Validation* section below. CCIT was replaced by sterility testing for the remainder of stability and corrective actions were taken in response to the failures. A torque specification was established and torque checks were added to the vialing record for each type of vial cap.

An additional torque study was performed and completed in 05/2018 in order to verify the operation of a new digital torque wrench, ensure the XQ Micro-Capper settings are at the appropriate range, validate the acceptability of the set torque range specification, and ensure shipping and handling do not impact container closure integrity. All testing results were found to be acceptable, including the change in torque after shipping as well as the CCIT performed by a third-party lab after shipping.

Laboratory Controls

Asteria uses two contract laboratories for the following:

Dynalabs, LLC 2727 Chouteau Avenue St. Louis, MO 63103	Finished product release testing Stability testing
ARL Bio Pharma 840 Research Parkway, Suite 546 Oklahoma City, OK 73104	Environmental monitoring micro testing Media growth promotion testing Raw material USP testing

Finished product is tested for potency, sterility, and endotoxins. Samples are taken at random after the product has returned from terminal sterilization. A total of 26 vials are sampled including 1 for endotoxins, 5 for potency, and 20 for sterility testing. All laboratory test results are received and reviewed by Asteria prior to finished product release.

Stability & Method Validation

Asteria contracted method validation and stability to be performed for the highest and lowest strengths of testosterone and estradiol pellets at Dynalabs. Their stability program is outlined in SOP PRD 05, Assignment of BUD (**exhibit 26**).

Method validation included validation extension (potency validation), endotoxin validation per USP 85, and sterility validation per USP 71. Significant concerns were noted with the test method used for sterility testing of the pellets as described in *Observation 2*.

The stability studies for each product and strength included potency, endotoxin, sterility, identification, weight checks, and CCIT. Major testing timepoints included initial, 60 days, 90 days, and 180 days. The following lots of product were placed on stability:

Estradiol	Lot	Dynalabs Sample ID	Comments
6 mg	04252017@1	W-1-34	---
6 mg	04252017@2	W-1-35	---
6 mg	04252017@3	W-1-36	Potency OOS at 90 days: 89.4%
37.5 mg	02282017@4	W-1-5	CCIT OOS: 1/40 vials
37.5 mg	02282017@5	W-1-6	CCIT OOS: 1/40 vials
37.5 mg	02282017@6	W-1-7	---

Testosterone	Lot	Dynalabs Sample ID	Comments
12.5 mg	02272017@10	W-1-11	---
12.5 mg	02272017@11	W-1-12	---
12.5 mg	02272017@12	W-1-29	---
200 mg	02272017@7	W-1-30	---
200 mg	02272017@8	W-1-31	CCIT OOS: 1/40 vials
200 mg	02272017@9	W-1-32	CCIT OOS: 6/40 vials Potency OOS at 126 days: 88.94%

Based on the testing performed, the expiry for all pellets is 180 days. The CCIT OOS findings are discussed in the *Container Closure Integrity Testing* section above. The potency OOS findings are discussed in the *Out of Specification Results* section below. No other concerns were noted with the design of the study or the findings.

During the inspection, I asked why no on-going stability studies had been initiated and was informed they were waiting for their first FDA inspection because it will expand their ability to distribute to other states. Ms. Kutz committed to beginning the next study within a month after the close of the current inspection.

Out of Specification Results

No OOS had been identified from release testing at the beginning of the inspection, though one occurred at the end of the inspection for Estradiol 6 mg, Lot 05222018@3. This should be reviewed during the next inspection.

OOS results were reported during the stability studies for both estradiol and testosterone. Stability batches were not released for distribution. During review of the testosterone OOS investigation, I noted the root cause was most likely due to laboratory error and concurred with the invalidation of the results. For the estradiol pellet OOS, I found that it had been invalidated without adequate supporting evidence as described in *Observation 4*.

503B Coverage

Asteria Health sells their products to clinicians only and they require each have a medical license, DEA license, and state license to place an order. They do not wholesale their products and they do not fill prescriptions. They currently only sell to clinicians in Alabama and Mississippi.

Licensed Pharmacist Supervision

There are currently three pharmacists employed at Asteria Health, including the most responsible individual, Mr. Fixler. There are currently no pharmacy technicians. Mr. Fixler is the PIC and is responsible for the majority of production activities to this point. His licenses are attached in **exhibit 5**. Mr. Larry Stephens is currently the secondary pharmacist and his licenses are attached in **exhibit 6**. Mr. Jon Morrow has performed a significant amount of work for Asteria, but is currently transitioning to a 503A pharmacist role. His licenses are attached in **exhibit 7**.

State Pharmacy Licensure

Asteria Health holds the following licenses (**exhibit 4**):

Agency/State	License Type	License Number	License Expiration
DEA	Manufacturer	RF0532362	9/30/2018
Alabama	Manufacturer	195381	12/31/2018
Alabama	Pharmacy	113486	12/31/2018
Georgia	Non-Resident Pharmacy	PHNR000899	6/30/2019
New York	Non-Resident Pharmacy	031712	12/31/2018

Drug Reporting

Asteria Health has submitted their drug listing at each required time point since they registered as an outsourcing facility.

Bulk Drug Substances

Estradiol and testosterone are the two APIs used at Asteria Health. They are supplied by vendors registered with the FDA and accompanied by COAs. Examples of COAs are shown in **exhibit 25**. No drug products appear on the withdrawn or removed from market listing. SOP RMS 01, Incoming Material & Component Receiving, Inspection, and Labeling, Version 2, Effective 1/15/18 (**exhibit 32**), requires materials be accompanied by a COA or COC.

SOP MSP 03, Material Supplier Approval, Version 1, Effective 9/1/2017 (**exhibit 33**), describes the requirements for suppliers of raw materials, though does not explicitly require they be FDA registered. This was not identified during the inspection, so it was not discussed with management.

Compounded Drug Labeling and Containers

No deficiencies were identified from review of the drug product labeling and containers. Examples of finished product labeling for each product type and strength are shown in **exhibit 30.** SOP PRD 01, Finished Product Labeling, Version 1, effective 10/31/2017 **(exhibit 31)** describes finished product labeling requirements and the requirement to include a copy in the batch record.

Adverse Event Reporting

Asteria has a complaint procedure in place, but does not explicitly require review of complaints for adverse events or define timelines for filing MedWatch reports. See *Observation 5* for additional details.

MANUFACTURING CODES

Asteria's products are assigned batch codes via PK Compounding Software. They consist of a date and consecutive number. For example:

06302018@3, which represents:

06 = Month (MM)
30 = Day (DD)
2018 = Year (YYYY)
@ = Signifier between the date and consecutive number (does not change)
3 = 3rd batch code generated on that day (Begins with 1 each day)

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically, during electron beam (e-beam) sterilization validation,

a. The bioburden and sterility method validation and suitability testing used for dose verification testing were not performed using testosterone and estradiol pellets made by your firm.
b. The sterility and bioburden testing methods do not evaluate the entirety of each implantable pellet, only the external surfaces.

Reference: 21 CFR 211.113(b)

Supporting Evidence & Relevance:

The Dose Verification Protocol for Asteria Health (Medizap) – Drug Pellet Family, Protocol No. Steri-Tek DVP004, approved on 3/31/2017, is attached as **exhibit 8.** This executed protocol

summarizes the data used to verify the e-beam dose used to sterilize Asteria Health's 200 mg testosterone pellets and 50 mg estradiol pellets. These are the maximum strengths of each product type.

ISO 11137-2:2012, Method VD_{max}^{25} was used as the basis for the sterilizing dose. Per this guidance, bioburden testing is first performed for 10 units and then sterility testing is performed after sterilization. Testing is performed per methods described in ISO 11737 by Pacific BioLabs (PBL), the contract lab for Steri-Tek. The bioburden test method requires a Bioburden Recovery Study and the sterility test method requires Bacteriostasis/Fungistasis Testing (comparable to method suitability testing).

a. During review of data, I found the bioburden recovery and suitability testing were not performed using Asteria's products. The summarized testing results and the referenced laboratory documents are outlined in the table below:

Asteria bioburden testing summary – Testosterone	**Exhibit 8, page 5**
Bioburden Analysis Study 17A0272S-M01 Testosterone Pellet 200 mg Made by Asteria Health	**Exhibit 8, page 15**
Bioburden Recovery Study Study 15B0102S-M01 Testosterone Pellet 200 mg Made by Wells Pharmacy Network, LLC	**Exhibit 9, page 1**
Asteria bioburden testing summary – Estradiol	**Exhibit 8, page 6**
Bioburden Analysis Study 17A0271S-M01 Estradiol Pellet 50 mg Made by Asteria Health	**Exhibit 8, page 17**
Bioburden Recovery Study Study 15L0323S-M01 Estradiol Pellet 75 mg Made by Westcliff Compounding Pharmacy	**Exhibit 9, page 3**
Asteria sterility testing summary – Testosterone	**Exhibit 8, page 9**
VD Max Dose Audit Study 17C0058S-M01 Testosterone Pellet 200 mg Made by Asteria Health	**Exhibit 8, page 11**
Bacteriostasis/Fungistasis Test Study 15B0103S-M01 Testosterone Pellet 200 mg Made by Wells Pharmacy Network, LLC	**Exhibit 10, page 1**

Asteria sterility testing summary – Estradiol	**Exhibit 8, page 9**
VD Max Dose Audit Study 17C0059S-M01 Estradiol Pellet 50 mg Made by Asteria Health	**Exhibit 8, page 13**
Bacteriostasis/Fungistasis Test Study 15L0318S-M01 Estradiol Pellet 50 mg Made by Pavilion	**Exhibit 10, page 3**

Sterility and bioburden testing methods were not verified as being acceptable for Asteria Health's products prior to their use for dose verification testing.

b. Both methods used are performed by direct inoculation of the hormone pellets. PBL's methods include SOP 14B-11, Revision 7A.01, Bioburden Testing, effective 8/26/16 (**exhibit 11**) and SOP 14B-13, Revision 4C.00, Sterility Testing for AAMI Dose Studies or Tests Utilizing One Medium, effective 10/14/16 (**exhibit 12**). The results for bioburden and sterility are only representative of microorganisms on the exterior surfaces of the pellets. There is no evaluation of the entire pellet, which is intended to completely dissolve in patients sub-dermally.

Discussion with Management:

Management understood the concerns and promised correction.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Specifically, sterility testing of hormone pellets during release testing only provides information for the exterior surfaces of the implantable pellets. There is no evaluation of the entire pellet.

Reference: 21 CFR 211.160(b)

Supporting Evidence & Relevance:

Each batch of pellets is sampled for release testing which includes potency/purity, endotoxin, and sterility testing. Release testing is performed by Dynalabs, LLC, and their sterility test method, MIC 16, Sterility Testing, Version 3, Effective 11/16/2015, is attached as **exhibit 13**. This version of the method was used during the stability study completed for hormone pellets.

Sterility validation was performed during stability testing. Per the Sterility Validation record for Estradiol 37.5 mg pellet (**exhibit 14, page 1**), and Testosterone 200 mg pellet (**exhibit 14, page 2**), Dynalabs used Direct Inoculation for validation activities. Ms. Kutz confirmed the same method is being used for their routine sterility testing. Testing results are not representative of the entire pellet, only the external surfaces.

Although this was not discussed during the inspection, it appears endotoxin testing also only evaluates the exterior surfaces of the pellets.

Discussion with Management:

Ms. Kutz explained they would be moving to parametric release of product and would no longer be performing sterility testing for the release of each batch. She stated she understood the method in use is not representative of the entire pellet and committed to correcting this if they perform sterility testing in the future.

OBSERVATION 3

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

Specifically, the equipment cleaning process has not been validated to ensure there is no cross-contamination between the hormone active pharmaceutical ingredients (APIs), testosterone and estradiol. The CST Stokes Pellet Press, Model 511, is used for both API products and poses the highest risk for cross-contamination due to non-dedicated product contact parts. Other equipment used with both APIs include powder control hoods, analytical balances, and calipers.

Reference: 21 CFR 211.67(a)

Supporting Evidence & Relevance:

Equipment at Asteria Health which is exposed to both testosterone and estradiol include:

AST #	Description	Manufacturer	Model	Location	Contact
AST 001	Powder Hood	Germfree	CSED-6SS	Room 17	Indirect
AST 002	Powder Hood	Germfree	CSED-6SS	Room 19	Indirect
AST 004	Analytical Balance	O'Haus	Voyager Pro 114CN	Room 19	Indirect
AST 005	Pellet Press	CCS, LLC	Stokes 511	Room 19	Direct
AST 006	Analytical Balance	O'Haus	Explorer EX1103N	Room 17	Indirect
AST 013	Calipers	Mitutoyo	CD 6" ASX	Room 19	Direct
AST 023	Powder Hood	LabConco	Xpert	Room 9	Indirect
AST 027	Analytical Balance	O'Haus	Explorer EX423N	Room 9	Indirect

Room 9 is used for incoming material sampling activities, Room 17 is used for powder blend activities, and Room 19 is used for pelleting activities.

For the pellet press, the dies used are product specific and are not shared between the two different hormone products. Equipment which is non-dedicated includes the die table, the feed shoe, and the hopper.

Although SOP CMP 07, General Compounding Cleaning and Restocking, Version 1, Effective 9/7/2017 (**exhibit 15**), states that equipment is cleaned per respective equipment procedures, there are few details for the cleaning of the pellet press within its equipment procedure. SOP EQP 08, CST Stokes Model 511 Pellet Press, Version 1, Effective 9/7/2017 (**exhibit 16**), states dies are cleaned with warm water and food grade or better detergent (step 21) and isopropyl alcohol (IPA) wipes are used for the hopper, feed cup, and metal surfaces of the press (step 22). There are no additional details for the cleaning of the press.

Cleaners used at Asteria Health include CiDehol 70 (sterile 70% IPA solution), HYPO-CHLOR 0.52% (sterile sodium hypochlorite solution), and DECON-SPORE 200 Plus (sterile peracetic acid and hydrogen peroxide solution). 70% IPA is the primary cleaner for all equipment and HYPO-CHLOR was added into use for painted and acrylic surfaces. DECON-SPORE is used for facility cleaning.

Discussion with Management:

Management understood the concerns and committed to completing a study to verify their cleaners are capable of removing traces of each hormone. However, I was provided with a written response to this observation later (**exhibit 17**) and it is not clear if they are still committed to completing cleaning validation. Although a lot of information is discussed in this response, it does not adequately substitute for information which would be gathered through a study. For example, in point 7, the argument is made that the presence of each hormone would be detected during potency testing. From the attached documentation, it shows the HPLC set-up for potency testing is similar between both hormones, except the detector for estradiol testing uses UV at 218 nm (**exhibit 17, page 4**) whereas testosterone testing uses UV at 245 nm (**exhibit 17, page 8**). There is no assurance both APIs are detectable at both wavelengths.

At the end of the inspection, Ms. Kutz also informed me they are in the process of performing IQ for a different pellet press, AST 090, Natoli, Model NP-P20A, which they intend to use exclusively for testosterone. She explained they are now intending to use separate presses for each of their hormone products.

OBSERVATION 4

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. Specifically, the assessment of the investigation into the assay failure of an Estradiol 6 mg Pellet, Lot

04252017@3, at the 90-day time-point lacks evidence to support invalidation of the out-of-specification (OOS) result.

Reference: 21 CFR 211.192

Supporting Evidence & Relevance:

Asteria Health's BUD Assignment Report for Estradiol Pellets, 6 mg – 37.5 mg, dated 1/15/2018 (**exhibit 18**), was generated to support the 180-day expiry based on the data generated from stability data. In the section describing Study Details, an assay failure at day 90 for Lot 04252017@3 is described and invalidated.

The report states, "Despite the laboratory being unable to perform a fully FDA compliant investigation, the weight of 1 pellet being atypical compared all other pellet weights in multiple stability studies, a confirmed laboratory history of 2 identical failures in the previous 3 weeks, and Asteria Health records showing each pellet was weighed and verified during compounding, the laboratory posted the original failing result and stated there was insufficient evidence to continue investigating, or set aside the original result" (**exhibit 18, page 2**). Asteria concludes the OOS was due to a laboratory attributable error and the Estradiol 6 mg Pellets are stable.

I found numerous issues with these conclusions during my review of the data available.

Regarding the concerns with the lab investigation:

> The third-party lab, Dynalabs, was unable to perform a complete investigation because they discarded the original dilution and the HPLC vial solution, however, they still had the original stock solution.
>
> Per Dynalabs Investigation Report No. 15607 (**exhibit 18, page 13**), on 7/24/2017, day 90, Lot 04252017@3 was found to have an assay of 89.4% with a specification of 90.0 – 110.0%. On 7/25/2017, the original stock solution was re-diluted, injected, and found to have an assay of 89.6%. Per the report, the original stock solution was made with 2 pellets weighing 5.9 mg and 5.7 mg. The original dilution and HPLC vial solution were discarded, so could not be re-injected as part of the investigation. The report states no laboratory error was identified and concludes the irregular pellet weights caused the out-of-specification (OOS) result (**exhibit 18, page 15**).
>
> Although the investigation conclusion is not actually conclusive because they were unable to ensure no errors occurred from the original dilution or HPLC vial, the results from the reinjection of the original stock solution suggests the original result may be accurate. There is no obvious lab error from this report.

Regarding the conclusion that there is "a confirmed laboratory history of 2 identical failures in the previous 3 weeks":

This is not an accurate statement. It appears the 2 other failures referenced in this report are for an Asteria Testosterone 12.5 mg Pellet, Lot 0222017@2, with a low assay OOS (Dynalabs Investigation Report No. 15475) and another estradiol assay OOS in the same run as Lot 04252017@3 (Dynalabs Investigation Report No. 15598).

The testosterone assay failure, per Investigation 15475, appears to be the result of laboratory error (**exhibit 19**). The stock solution, original dilution, and HPLC vial were all tested in this case and the result appears to be poor dissolution in the original stock solution due to the variability seen during testing. This is not identical or similar to their estradiol investigation because variance would have been observed in the re-injection of the stock solution.

The estradiol assay OOS in Investigation 15598 is for pellets owned by another company; Asteria is not privy to the information from this investigation. This OOS is referenced in Section 3A, Question 7 of the investigation (**exhibit 18, page 13**). There is no way for Asteria to know whether or not this OOS is identical, or even similar, to their estradiol investigation.

Regarding the statement, "...Asteria Health records showing each pellet was weighed and verified during compounding...":

This is not an accurate statement. Per management, they weigh 100% of their pellets prior to vialling, so the pellet weights reported by the lab of 5.9 mg and 5.7 mg are not possible. The batch documentation for Lot 04252017@3 does not include pellet weights. I asked how they could come to this conclusion and was informed the pellet weights were recorded, just not using controlled forms. Management had to dig through boxes to locate the records. Pellet weight records were found and provided on 6/18/2018.

From batch documentation for Estradiol, Lot 04252017@3, a total of 325 pellets were made (**exhibit 20, page 1**) and a total of 325 were sent for sterilization (**exhibit 20, page 3**). Per the pellet weight records provided, only 321 pellet weights were recorded, including 1 pellet which was discarded for being overweight (**exhibit 21**). At least 5 pellet weights were not documented. Due to the lack of procedure and documentation, there is no way to know exactly how many pellets were made, how many were weighed/discarded, and how many were not weighed at all. Asteria cannot conclude each pellet weight was verified during compounding.

Asteria invalidated the stability assay OOS for Estradiol, Lot 04252017@3, without any supporting data.

Discussion with Management:

Ms. Kutz was surprised this observation was on the FDA 483, although we had discussed the issues I found during the inspection. She believed the data she obtained during the inspection, which she used to more adequately invalidate the data, was sufficient to address the concern. She was able to obtain chromatograms upon contacting DynaLabs and concluded the integration parameters were wrong and caused the failures to occur. When comparing the integration parameters for the reference standard curves versus the sample curves, Ms. Kutz stated it is apparent the sample curves do not include the entirety of the beginning of the curve. See **exhibit 22** for an updated investigation and new supporting evidence.

I explained that corrections made during an inspection do not negate the significance of observations. I pointed out that her most recent reason for invalidating the data is in no way supported by her original rationale described in the report. I did not re-evaluate the adequacy of this updated investigation during the inspection.

OBSERVATION 5

Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

Reference: 21 CFR 211.198(a)

Supporting Evidence & Relevance:

The Asteria complaint procedure does not include instructions for evaluation of whether a complaint represents an adverse drug event. Per SOP GMP 11, Customer Complaints and Inquiries, Version 2, Effective 11/1/2017 (**exhibit 23**), the PIC and Quality will perform required FDA Medwatch notifications, but it lacks direction to evaluate each complaint, definitions for adverse events and serious adverse events, and the timelines for reporting each event type.

Discussion with Management:

Management understood and promised correction.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection on 7/10/2018, I held a closing meeting with the following people present:

- William (Bill) E. Fixler, Co-Owner & Pharmacist in Charge (PIC)

- Wayne Fixler, Co-Owner & Compliance/Operations Manager
- Carla Kutz, Quality & Regulatory Affairs Manager
- Larry Stephens, Pharmacist
- Jeanne Cochran, Customer Service & Administrative Assistant
- Todd Brooks, Drug Inspector, AL Board of Pharmacy
- Dorcas Ann Taylor, CDER Compliance Officer (via teleconference)

Each item listed on the FDA 483 was read to the above individuals. I encouraged management to discuss each item and to ask any questions or for clarification, if needed. Management promised to respond to each observation in writing within 15 business days. I stated our inspection is not considered all-inclusive. I explained that these observations are in our judgment and are not necessarily those of the agency; the agency will make their final compliance determination after reviewing all information. I stated that legal sanctions available to the FDA for non-compliance include untitled letter, warning letter, injunction, seizure, and civil money penalties.

In addition to the FDA 483, I verbally discussed the following observations with management:

1. I discussed the requirement to produce products intended to be sterile under a controlled environment, minimum of ISO 8. I explained their environmental data supports the production areas being maintained at ISO 7 and ISO 8 conditions, but their EM program requires additional sampling to provide enough meaningful data. Management understood my concerns and promised correction.

No other discussions were held and the inspection was concluded. We thanked management for their time and cooperation during this inspection.

SAMPLES COLLECTED

No samples were collected.

ADDITIONAL INFORMATION

The officially sealed original copy and unsealed working copy discs containing photographs taken and electronic documentation collected during the inspection are filed with the unlabeled exhibits and attachments.

EXHIBITS

Exhibit 1	Organizational Chart	1 page
Exhibit 2	Production Record (No R&D Batches)	1 page
Exhibit 3	Facility Diagrams	4 pages
Exhibit 4	Pharmacy Licenses	5 pages
Exhibit 5	Pharmacist Licensure – William (Bill) Fixler	14 pages
Exhibit 6	Pharmacist Licensure – Larry Stephens	10 pages

Exhibit 7	Pharmacist Licensure – Jon Morrow	2 pages
Exhibit 8	Dose Verification Protocol – Asteria Health (Medizap)	18 pages
Exhibit 9	Pacific BioLabs – Bioburden Recovery Validation	4 pages
Exhibit 10	Pacific BioLabs – Bacteriostasis/Fungistasis Testing	4 pages
Exhibit 11	Pacific BioLabs – SOP 14B-11, Rev 7A.01, Bioburden Testing	14 pages
Exhibit 12	Pacific BioLabs – SOP 14B-13, Rev 4C.00, Sterility Testing for AAMI Dose Studies	6 pages
Exhibit 13	Dynalabs – SOP MIC 16, Ver 3, Sterility Testing	5 pages
Exhibit 14	Stability Testing – Sterility Validation Testing	6 pages
Exhibit 15	SOP CMP 07, Ver 1, General Compounding Cleaning and Restocking	1 page
Exhibit 16	SOP EQP 08, Ver 1, CST Stokes Model 511 Pellet Press	4 pages
Exhibit 17	Firm Response to Cleaning Observation	30 pages
Exhibit 18	Estradiol Stability Data	34 pages
Exhibit 19	Testosterone Stability Investigation 15475	3 pages
Exhibit 20	Estradiol, Lot 04252017-3, Batch Record	3 pages
Exhibit 21	Estradiol, Lot 04252017-3, Pellet Weights	3 pages
Exhibit 22	Firm Response to Estradiol Failure Investigation Observation	56 pages
Exhibit 23	SOP GMP 11, Ver 2, Customer Complaints and Inquiries	3 pages
Exhibit 24	SOP GMP 04, Ver 1, Recall	5 pages
Exhibit 25	API and Excipient COAs	4 pages
Exhibit 26	SOP PRD 05, Ver 1, Assignment of BUD	2 pages
Exhibit 27	SOP CMP 09, Ver 1, Environmental Monitoring	3 pages
Exhibit 28	SOP NSC 05, Ver 2, Terminally Sterilized & Non-Sterile Compounding Environmental Monitoring (with EM Sampling Map)	4 pages
Exhibit 29	EM Data and Trending	4 pages
Exhibit 30	Finished Product Labeling Examples	1 page
Exhibit 31	SOP PRD 01, Ver 1, Finished Product Labeling	2 pages
Exhibit 32	SOP RMS 01, Ver 2, Incoming Material Receiving, Inspection, and Labeling	3 pages
Exhibit 33	SOP MSP 03, Ver 1, Material Supplier Approval	2 pages

ATTACHMENTS

FDA 482, Notice of Inspection, 6/12/2018	3 pages
FDA 483, Inspectional Observations, 7/10/2018	3 pages
Electronic Regulatory Notes – S. Bradley	21 pages
CDER Assignment, 1/30/2018	39 pages
CDER Assignment Opioids Addendum, 3/6/2018	2 pages

Signatures

Samantha J. Bradley

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=PIV, serialNumber=D72A10D821086C4E542D25A16859010849C10A02872A8243F9
Date: 2018.09.17 14:10:13 -05'00'

Samantha J. Bradley, Certified Drug Investigator

Dorcas A. Taylor -S5

Digitally signed by Dorcas A. Taylor -S5
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000337671, cn=Dorcas A. Taylor -S5
Date: 2018.09.28 13:12:11 -04'00'

Dorcas Ann Taylor, CDER Compliance Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/12/2018-07/10/2018
	FEI NUMBER 3010348724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William E. Fixler, Co-Owner & Pharmacist in Charge	
FIRM NAME FH Investments Inc. dba Asteria Health	STREET ADDRESS 7004 Champion Blvd, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35242	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically, during electron beam (e-beam) sterilization validation,

a. The bioburden and sterility method validation and suitability testing used for dose verification testing were not performed using testosterone and estradiol pellets made by your firm.
b. The sterility and bioburden testing methods do not evaluate the entirety of each implantable pellet, only the external surfaces.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Specifically, sterility testing of hormone pellets during release testing only provides information for the exterior surfaces of the implantable pellets. There is no evaluation of the entire pellet.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	07/10/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/12/2018-07/10/2018
	FEI NUMBER 3010348724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William E. Fixler, Co-Owner & Pharmacist in Charge	
FIRM NAME FH Investments Inc. dba Asteria Health	STREET ADDRESS 7004 Champion Blvd, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35242	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 3

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

Specifically, the equipment cleaning process has not been validated to ensure there is no cross-contamination between the hormone active pharmaceutical ingredients (APIs), testosterone and estradiol. The CST Stokes Pellet Press, Model 511, is used for both API products and poses the highest risk for cross-contamination due to non-dedicated product contact parts. Other equipment used with both APIs include powder control hoods, analytical balances, and calipers.

OBSERVATION 4

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OBSERVATION 5

Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

***DATES OF INSPECTION:**

06/12/2018 (Tue), 06/13/2018 (Wed), 06/14/2018 (Thu), 06/15/2018 (Fri), 06/18/2018 (Mon), 06/19/2018 (Tue), 06/20/2018 (Wed), 7/2/2018 (Mon), & 7/10/2018 (Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	07/10/2018

MWD INSPECTION

☐ Not Licensed

AL License Number	DEA Number	Status
195381	RF0532362	Closed - Compliant
Contact1	**Contact1 Email**	**Contact2**
Bill Fixler		Bill Fixler
Contact2 Email	**Inspection Type**	**Inspection Date**
	Routine	09/25/2023

Inspector Name

Mdelk

Type Operations

- ☑ M/W/D (Prescription Drugs or Controlled Substances
- ☐ M/W/D (Veterinarian)
- ☐ M/W/D (Precursor Chemicals)
- ☐ (Repackager) 34-23-32 (b) requires pharmacist for repackaging operations.

☐ Case nber

ADDRESS INFORMATION

Address 1 : 7004 CHAMPION BLVD

Address 2 : SUITE 100

City : BIRMINGHAM

State / Zip : AL 35242

STORAGE CONDITIONS

Facility must have proper lighting.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
The storage area must be kept free from infestation by insects, rodents, birds or vermin of any kind and must be maintained in a clean and orderly manner.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
All drugs or medicines must be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such drugs or medicines or with the requirements in the current edition of an official compendium. If no storage requirements are established for a drug or medicine they may held at "controlled" room temperature as defined in an official compendium to help ensure the identity, strength, quality, and purity of the same are not adversely affected.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
Must have appropriate manual, electromechanical, or electronic temperature and humidly recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
A separate quarantine storage section must be provided for drugs or medicines that are deteriorated, outdated, misbranded, or otherwise adulterated, or that are in immediate or sealed secondary containers that have been opened.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)
Drugs shipments must be visually examined for identity and to prevent the acceptance or distribution of contaminated or damaged products.	☑ Yes	☐ No	☐ N/A	680-X-2-.23 (2a)

FACILITIES

Must be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

Buildings must meet all applicable federal, state and local standards. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

A facility may not be located in a residence. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2b)

SECURITY

Facility secure from unauthorized entry. ☑ Yes ☐ No ☐ N/A

Key pad locked entry door.
680-X-2-.23 (2c)

Facility must be equipped with an alarm system to detect entry after hours. ☑ Yes ☐ No ☐ N/A

CSV ALARM
680-X-2-.23 (2c)

Must ensure access from outside their premise is reduced to a minimum and well controlled. This includes but not limited to, the installation of adequate lighting at the outside perimeter. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Internal security policies to provide reasonable protection against theft by personnel. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Policies for protection against computer theft and crimes. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2c)

Entry to areas where drugs are held shall be limited to authorized personnel. ☑ Yes ☐ No ☐ N/A

Secured at all times.
680-X-2-.23 (2c)

RECORD KEEPING REQUIREMENTS

Drug Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. Shall consist of the following:
1. The source of all drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

2. The identity and quantity of the drugs received and distributed or disposed of. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

3. The dates or receipt and distribution or disposition of the drugs. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

Inventories and records must be kept 2 years following disposition of the drugs, for inspection and photocopying. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

All records described in this rule, that are kept on site or that can be immediately retrieved by computer or other electronic means shall be readily available for inspection during the retention period. ☑ Yes ☐ No ☐ N/A
680-X-2-.23 (2e1)

Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by authorized personnel.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (2e1)

All charge back transactions must be maintained separately from al other records.

☑ Yes ☐ No ☐ N/A

Reviewed multiple physicians orders.

680-X-2-.23 (2e1)

Copies of records and reports required by DEA concerning the increases in purchases or high volumes purchased by pharmacies, shell be forwarded to the Board of Pharmacy.

☑ Yes ☐ No ☐ N/A

Last DEA INSPECTION 9-22-21.

680-X-2-.23 (2e1)

WRITTEN POLICIES AND PROCEDURES

A procedure to ensure that wholesale drug distributors prepares for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or any other situation of local, state, or nation emergency.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.i)

A written procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs and shall be maintained for two (2) years.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.ii)

A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation if temporary and appropriate.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iii)

A procedure to be followed for handling recalls and withdrawals of drugs which shall be adequate to deal with recalls and withdrawals due to:
1.Any action initiated at the request of the FDA or other Federal, State or Municipal law enforcement or other governmental agency including the Alabama State Board of Pharmacy.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

3. Any action undertaken to promote public health and safety by placing existing merchandise with an improved product or new package design.

☑ Yes ☐ No ☐ N/A

680-X-2-.23 (g1.iv)

CHEMICAL PERMIT HOLDERS

A licensee shall make an accurate and legible record of any transaction of listed precursor chemicals and maintain such record together with the following records for a period of at least two (2) years:
1. Inventory on hand

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

2. Purchase receipts.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

3. Manufacturing records including the date and quantity of any listed precursor chemicals manufactured, the quantity of listed precursor chemicals used in the manufacturing any other substance or product, and the inventory on hand of listed precursor chemicals after the manufacturing of any substance or product

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

4. Copies of the Board of Pharmacy licenses or permits.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

5. Records of substance disposal.

☐ Yes ☐ No ☑ N/A

20-2-182 (d)

COMMENTS

503B SELL MANUFACTURING AND SELLS ESTRADIOL PELLETS AND TESTOSTERONE TO PHYSICIANS OFFICES. WHSE SPECTRUM, VIEWED CS INVENTORY 1-15-2023. UNIT/GRAMS. DEA RF0532362. FEI 3010348724. NABP ACCREDITATION.2023. RPH BILL FIXLER 14696 RPH ROBIN FIXLER 14698.

Business Lookup Online Application

This is primary source verification

Date Printed : 3/18/2024

License Information

Name : F H INVESTMENTS, INC dba ASTERIA HEALTH

License # : 195381

License Type : 503-B Outsourcing Facility

License Status : Active

Issue Date : 11/13/2017

Expiration Date : 12/31/2024

Discipline : N

Address : 7004 CHAMPION BLVD SUITE 100

City : BIRMINGHAM

State : AL

Zip : 35242

Designated Representative :

Controlled Substance Information

Status : Active

Issue Date : 01/01/2023

Expiration Date : 12/31/2024

Business Lookup Online Application

This is primary source verification

Date Printed : 3/18/2024

License Information

Name : F H INVESTMENTS, INC dba ASTERIA HEALTH

License # :113486

Supervising Pharmacist: WILLIAM EARL FIXLER

Email Address: waynefixler@asteriahealth.com

License Type : Community Pharmacy

License Status : Inactive

Issue Date :12/16/2010

Expiration Date : 12/31/2020

Discipline :N

Address : 7004 CHAMPION BLVD SUITE 100

City :BIRMINGHAM

State :AL

Zip :35242

Designated Representative :

USP 795 : No

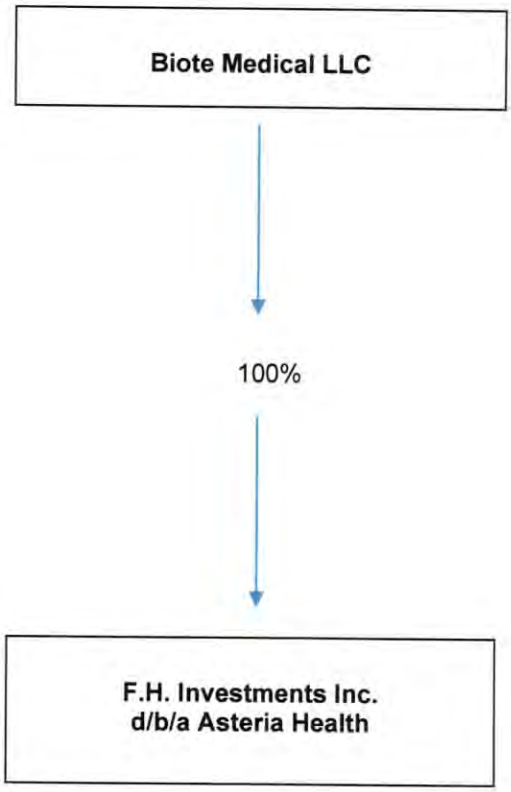
USP 797 : No

Controlled Substance Information

Status : Active

Issue Date :01/01/2019

Expiration Date :12/31/2020


Biote Medical LLC
100%
F.H. Investments Inc.
d/b/a Asteria Health

F.H. Investments Inc. d/b/a Asteria Health

Officer and Ownership Information for F.H. Investments Inc. d/b/a Asteria Health

F.H. Investments Inc. d/b/a Asteria Health
7004 Champion Blvd, Suite 100
Birmingham, AL 35242
FEIN: 27-2844223

F.H. Investments Inc. d/b/a Asteria Health has two officers:

Mary Elizabeth Conlon
Secretary and General Counsel
Home Address: [redacted] Dallas, TX 75205
DOB: [redacted]
Telephone: [redacted]
Email: Marybeth.Conlon@biote.com

Robert Peterson
Treasurer and CFO
Home Address: [redacted], Southlake, TX 76092
DOB: [redacted]
Telephone: [redacted]
Email: Bob.Peterson@biote.com

F.H. Investments Inc. d/b/a Asteria Health is wholly owned by its parent company, Biote Medical LLC.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: FH Investments Inc. d/b/a Asteria Health

NV Pharmacy or Outsourcing facility license # (if applicable): OUT00011

Physical Address: 7004 Champion Blvd, Suite 100

City: Birmingham State: AL Zip: 35242

Mailing Address (if different from physical address): same as above.

City: State: Zip:

Telephone: 205-995-0505 Toll Free # (NAC 639.708, NRS 639.23286): 855-771-0505

Fax: 205-995-0507 Contact Email: licensing@biote.com

Website: www.asteriahealth.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Musser

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20144

Name of Person with direct knowledge of compounding procedures: Christopher Musser

Email of Person with direct knowledge of compounding procedures: Christopher Musser

Telephone of Person with direct knowledge of compounding procedures: 205-995-0505

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

All products are terminally sterilized per ISO by electron beam exposure. All products are compounded in an ISO-8 environment, as required by FDA guidance for 503B for terminally sterilized products.

Estradiol Pellets: 6mg, 10mg, 12.5mg, 15mg, 18mg, 20mg, 22mg, 25mg and 37.5mg
Testosterone Pellets: 12.5mg, 18mg, 25mg, 37.5mg, 50mg, 62.5mg, 87.5mg, 100mg, 200mg and 303mg
Testosterone 60mg / Anastrozole 4mg Pellets
Testosterone 75mg / Anastrozole 4mg Pellets
Testosterone 100mg / Anastrozole 4mg Pellets
Testosterone 200mg / Anastrozole 10mg Pellets
Testosterone 87.5mg / Triamcinolone Acetonide 17.5mcg Pellets
Testosterone 100mg / Triamcinolone Acetonide 20mcg Pellets

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

USP compliant stability testing per ICH Q1 (R2). Products successfully passed established criteria for beyond use dating of 1 year.

6. What laboratory performs this additional testing?

Name: Dynalabs
Address: 2327 Shouteau Blvd
City: St. Louis State: MO Zip: 63103
Telephone: 1-800-DYNALABS

7. What is your procedure for visual inspection of compounded sterile products?

See attached PRD-04 for visual inspection of pellets.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip testing is performed quarterly for all employees entering the production rooms in triplicate. No media fill testing is possible since this is a dry granulation compressed into pellets.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Gloved fingertip testing is performed for all the employee's thumbs, left hand, and right hand. A 'set' is the group of 3 plates from one complete verification. If the set shows 3-4 cfu, the employee will be retrained and retested once. If the set shows 5 cfu or more, the employee will be retrained and repeat testing in triplicate. If failed again, they will be reassigned to a non-product contact function.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

See attached training modules for PIC (Pharmacist In Charge), Staff Pharmacist, TS Technician 1 and 2.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached cleaning procedures describing steps and frequency of clean and disinfectant validated. There are weekly and monthly cleaning forms that are completed as described, and CMP 07 describes cleaning and restocking.

12. Who performs the sterile compounding process at your facility?

Qualified and trained employees that have demonstrated competency and understanding of SOPs. In addition, there are two pharmacists on staff that oversee activities in the processing rooms.

13. Who is responsible and accountable for the sterile compounding process at your facility?

All employees are responsible for following SOPs governing the process, but the Pharmacist in Charge (PIC) is ultimately accountable for all products and that they were manufactured under cGMP processes.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All packages are sent through a 3PL supplier (FedEx) with a priority of not longer than 2-day express. In addition, shipping validation has been performed at both extreme temps (hot and cold) and showed no impact on the efficacy of the pellets.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? All hazardous compounding is performed in a biological safety cabinet (BSC-I) which is externally vented to the outside, physically separated from the other suites, meets ISO-8 guidelines for air changes per hour, and runs continuously.		
2. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? We do not provide any information to patients since the pellets are administered by a health care professional in a doctor's office or clinic setting. The clinic is responsible for the handling and disposal of hazardous or controlled substances and creating their SOPs and processes to adhere to DEA and OSHA regulations.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? See attached training modules for PIC (Pharmacist In Charge), Staff Pharmacist, TS Technician 1 and 2.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Testosterone 60mg / Anastrozole 4mg Pellets
Testosterone 75mg / Anastrozole 4mg Pellets
Testosterone 100mg / Anastrozole 4mg Pellets
Testosterone 200mg / Anastrozole 10mg Pellets

All of the products manufactured at this site are considered high risk compounding because they originate from non-sterile ingredients. In addition, Anastrozole is a Table 1 hazardous drug on the NIOSH list and the products containing Anastrozole are listed above.

2. What sterilization methods are utilized at your facility?

Asteria Health is a 503b compounding outsourcing facility and all of our pellets are terminally sterilized using e-beam technology at Steri-Tech.

3. Does your facility utilize biological indicators? ☐ Yes ☒ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Musser
Name of Person who Completed the Form

Pharmacist-in-Charge
Title

Signature (copies or stamps not accepted)

08/07/2024
Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ■ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04381	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ■ Other: ecommerce pet pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ■ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Agropec Trading, LLC DBA Allivet

Physical Address: 3250 W Ali Baba Ln, Suite A

City: Las Vegas State: Nevada Zip: 89118

Mailing Address (if different from physical address): 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Telephone: 305-999-5914 Toll Free # (NAC 639.708, NRS 639.23286): 877-500-9944

Fax: 877-500-9950 Contact Email: ani@allivet.com

Website: https://www.allivet.com/

Nevada Business License # (if applicable) NV20212250091

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Erast Tarangul

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09314

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Erast Tarangul	NV Pharmacist Registration #: Nevada 09314
Name: Danny Chang	NV Pharmacist Registration #: Nevada 14142
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Grandparent Entity - See attached corporate structure

Corporation Name: Tractor Supply Company

Mailing Address: 5401 Virginia Way

City: Brentwood State: TN Zip: 37027

Telephone: (615) 440-4000 Email: rmills@tractorsupply.com

Contact Person Name: Robert Mills

Date of SEC Registration: 02/17/1994 | SEC Registration Number: 000-23314 | Stock Exchange Symbol: TSCO

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Allivet, Inc.

Corporation/Organization Name: Agropec Trading, LLC dba Allivet

Mailing Address: 14540 NW 60th Avenue

City: Miami Lakes State: FL Zip: 33014

Telephone: 305-999-5914 Email: ani@allivet.com

Contact Person Name: Anabel Molinar

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the EVP, Officer (title) for Tractor Supply Company (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert Dean Mills

Print Name of Authorized Person

Robert Dean Mill

Original signature of Authorized Person (copies or stamps not accepted)

11/6/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, John Jairo Navas hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Officer (title) for Agropec Trading, LLC DBA Allivet (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18TH day of November, 2024

Notary Public

NOTARY PUBLIC
Expires 11/29/2025
Anabel Moliner
My Commission HH 203043
STATE OF FLORIDA

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Erast Tarangul Pharmacist Registration #: Nevada 09314

Pharmacy Name: Agropec Trading, LLC DBA Allivet

Initial each statement below to indicate you have read and agree with the following:

CT I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CT I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CT I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CT I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CT I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
N/A	N/A	N/A	N/A

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A	N/A	N/A	N/A	N/A	N/A

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

11/12/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Mills

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/8/24

Date

Board Use Only	Date Received: _____	Amount: 500.00 / VT# 34644

Allivet
www.allivet.com

November 13, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, Nevada 89521

Re: Agropec Trading, LLC dba Allivet

Nevada Pharmacy Application – Signed Statement of State Actions Explanation

This statement serves as an explanation in response to Section 3, Question 3: History of Company, on the Nevada Pharmacy application, which was answered "Yes."

Agropec Trading, LLC, doing business as Allivet, has been the subject of regulatory actions concerning its licenses in other states, specifically related to our Miami Lakes, Florida pharmacy.

A detailed summary of the state actions related to this matter is attached for your review.

I affirm that the above information and the attached documentation are true and correct to the best of my knowledge.

John Jairo Navas – Officer

Signature: _____

Date: 11/13/2024

Allivet
Your Ally in Pet Pharmacy Care

14540 NW 60th Ave
Miami Lakes, FL 33014
Phone 877-500-9944
Fax 877-500-9950
www.allivet.com

State Disciplinary Actions

1. **Oregon - 2008-0097 - 12/09/08**

   The case with the state of Oregon was opened on Dec 9th, 2008, and settled with a consent order dated February 18th, 2009. There was a civil fine of $750 due to Allivet shipping to Oregon in early 2008 without an out of state license. This was an unintentional oversight as Allivet was a new pharmacy and was in the process of obtaining all licenses.

2. **Indiana - 2011 IBP 0053 - 09/28/11**

   Allivet began shipping prescription orders into the state of Indiana while the pharmacy application was still in process. Because of that, Indiana sent a stop-ship order dated September 28th, 2011. Allivet received its out of state pharmacy license from the state of Indiana in December 2011 and was able to continue operating without any further issues.

3. **Alabama-16-L-0130 - 02/28/17**

   This action was a ***derivative action*** referencing the following disciplinary actions:

   - Oregon - 2008-0097 - 12/09/08
   - Indiana - 2011 IBP 0053 - 09/28/11

4. **Colorado - CO-2013-534 - 12/19/13**

   Allivet was fined $1,100 by Colorado for dispensing medications without a wholesale license to a veterinarian. At the time of the incident in 2011, Isoxsuprine was on manufacturer backorder, but Allivet had the product in stock. Due to the product's constrains Allivet was contacted by a veterinarian urgently requiring this medicine for his pet owners in Colorado. Allivet provided the medication, unaware of the wholesale licensing requirements. Allivet does not engage in any wholesale pharmacy transactions to ensure full compliance with state regulations.

5. **Alabama-AL-2015-001 - 10/10/15**

   Allivet applied for a Pharmacist-in-Charge (PIC) license with the Alabama Board of Pharmacy on November 10, 2014, to facilitate the renewal of its pharmacy license for 2015. Alabama scheduled a meeting for Allivet's pharmacist in February 2015, beyond the expiration date of the license on December 31, 2014. To address this, Allivet contacted the Board of Alabama to request an earlier meeting and to confirm that its renewal would not be affected by the schedule. During this time, it was assured that Allivet's pharmacy license would remain in good standing until the in-person meeting, and the Board's website indicated the license as active. Operating under this assumption, Allivet continued shipping products. When questioned about early 2015 shipments, Allivet explained that it believed it was permitted to do so based on prior communications. As a result, Allivet was fined $500 for shipping into the state without an Alabama-licensed Pharmacist-in-Charge.

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6. **Arkansas-AR-2015-049 - 10/13/15**

   In 2015, a technical issue in Allivet's system compromised the designated safety measures to prevent shipment of prescription items without active licenses. As a result, orders placed over the phone were processed and shipped into Arkansas without a valid license in 2015.

7. **Alabama-17-L-0050 - 05/18/17**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

8. **Colorado - 2018-6062 - 08/13/18**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

9. **Michigan-53-17-148216 - 06/25/18**

   Action I:
   In late 2008, Allivet changed locations and failed to report the change of location within 30 days to the Michigan Board of Pharmacy. This was an unintentional oversight as Allivet had just opened its pharmacy in 2007. At the following renewal date, Allivet noted the new address which triggered the action.

   Action II:
   This action was a ***derivative action*** referencing the following disciplinary actions:
   - Oregon - 2008-0097 - 12/09/08
   - Alabama-AL-2015-001 - 10/10/15
   - Arkansas-AR-2015-049 - 10/13/15

10. **Texas-K-17-031 - 07/09/18**

    Action I:
    This action was a ***derivative action*** referencing the following disciplinary actions:

    - Oregon - 2008-0097 - 12/09/08
    - Indiana - 2011 IBP 0053 - 09/28/11
    - Colorado - CO-2013-534 - 12/19/13

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Action II:
On September 1st, 2016, the Texas Board of Pharmacy changed the requirement for non-resident pharmacies to have a licensed Texas Pharmacist in Charge. Allivet immediately began the process to obtain licensure for its pharmacist, but due to the lengthy process, the license was not granted until May 2017. Therefore, due to the Texas regulatory change, Allivet operated without a Texas-licensed Pharmacist-in-Charge from September 1, 2016, to May 21, 2017. Currently, Allivet holds an active license and is in good standing with the state of Texas.

11. Illinois - 021930788 - 11/05/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Oregon - 2008-0097 - 12/09/08
- Indiana - 2011 IBP 0053 - 09/28/11
- Colorado - CO-2013-534 - 12/19/13
- Alabama-AL-2015-001 - 10/10/15
- Arkansas- AR-205-049 - 10/13/15
- Michigan-53-17-1481216 - 06/25/18
- Texas-K-17-031 - 07/09/18

12. Hawaii-RICO Case No. PHA 2019-79-L - 12/26/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Texas-K-17-031 - 07/09/18
- Michigan-53-17-148216 - 06/25/18

13. Alabama-19-L-0007 - 01/06/20

This action was a ***derivative action*** referencing the following disciplinary actions:

- Florida Case No. 2008-26608[1]
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Michigan-53-17-148216 - 06/25/18
- Alabama-16-L-0130 - 02/28/17
- Alabama-17-L-0050 - 05/18/17

[1] Original case was under a different pharmacy license, which has no impact or connection to Allivet's current license nor disciplinary history.

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14. Hawaii-RICO Case No. PHA 2020-168-L - 01/18/21

This action was a ***derivative action*** referencing the following disciplinary actions:

- Michigan-53-17-148216 - 06/25/18
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Illinois- 021930788 - 11/05/19

15. Nebraska - Censure Complaint #20190354 - 07/09/20

This censure derived from selling rabies vaccines to consumers in Nebraska, instead of the prescribing veterinarian. Allivet has since taken down the sales of all rabies vaccines across all 50 states to avoid similar circumstances where the Board changes its stance with this product. Dismissal order matter was approved by Hearing Officer on 07/09/2020.

16. Alabama - Consent Letter - 11/10/21

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20

17. Hawaii - RICO Case No. PHA2022-2-L - 05/25/22

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20
- Alabama - Consent Letter - 11/10/21

Non-Disciplinary Communications

1. Tennessee – Consent Letter – 01/25/2024 Case No. 2023026981

In June 2023, the company changed the Pharmacist in Charge (PIC) at its Miami facility and as required, notified each State Board of Pharmacy. Unfortunately, the notification sent to Tennessee contained an incorrect date, suggesting that there was a brief period when the Miami facility did not have a PIC. This was merely a clerical error. The company has provided all requested records to the Tennessee Board, along with an affidavit from the PIC, demonstrating compliance with PIC regulations at all times. On October 16, 2024, the Tennessee Attorney General for the Board of Pharmacy communicated that the case was closed. No discipline was imposed.

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2. **Missouri – Letter of Concern – 03/28/2024**

This action was a letter of concern related to the failure to report disciplinary action taken by Hawaii (RICO Case No. PHA2022-2-L; see 17 above). No discipline was imposed.

State of Florida
Department of State

I certify from the records of this office that AGROPEC TRADING, LLC is a limited liability company organized under the laws of the State of Florida, filed on February 22, 2017, effective December 9, 1993.

The document number of this limited liability company is L17000041105.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on January 4, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourth day of January, 2024

Secretary of State

Tracking Number: 6812209961CC

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Delaware

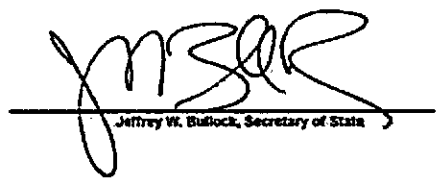
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TRACTOR SUPPLY COMPANY" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





949106 8300

SR# 20244239362

Authentication: 204897649

Date: 11-18-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

LIST OF OFFICERS

CURRENT OFFICERS

Allivet, Inc.
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

Agropec Trading, LLC
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

POST-CLOSE OFFICERS[1]

Tractor Supply Company[2]
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Seth Estep-Executive Vice President-Chief Merchandising Officer

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•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

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•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

[1] Note that the list of officers for Allivet, Inc. and Agropec Trading, LLC is a comprehensive list. However, the list of officers for Tractor Supply is an abbreviated list.
[2] A comprehensive list of officers of Tractor Supply's can be found on the Investor Relations webpage at: https://ir.tractorsupply.com/investor-relations/governance/executive-management/default.aspx

List of Top four Stockholders and their percentage of Ownership:

Agropec Trading LLC dba Allivet
Allivet, Inc. – 100%

Allivet, Inc.
Tractor Supply Company – 100%

Tractor Supply Company
Vanguard Group - 11.86%
Black Rock, Inc. – 8.93%
Capital international Investors – 6.09%
Capital World Investors – 5.42%

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•John J. Navas-Officer

Attachment 3

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Corporate Structure

Pre-Close

Allivet, LLC
(the "Seller")

Allivet, Inc.
(the "Company")

Agropec Trading, LLC
(the "Operating Subsidiary")

Pharmacy Licenseholder

Post-Close

Tractor Supply Company

Allivet, Inc.
(the "Company")

Agropec Trading, LLC
(the "Operating Subsidiary")

Corporate Structure



Attachment 2

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Agropec Trading, LLC dba Allivet

Pharmacy/Wholesaler License # (if applicable): Nevada Pharmacy License # PH04381

Physical Address: 3250 W Ali Baba Ln Suite A

City: Las Vegas State: Nevada Zip: 89118

Mailing Address (if different from physical address): 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Telephone: 877-500-9944 Website: www.allivet.com

Licensing Company Email: compliance@allivet.com

Section 2: Personal Information

First: Christopher Middle: Erast Last: Tarangul

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: 89138

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		9/73-6/77	
Address	**City**	**State**	**Zip**
1985 Zonal Avenue	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Connecticut		9/71-1/73	
Address	**City**	**State**	**Zip**
8 Gilbert Road	Storrs	CT	06268
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		9/69-6/71	
Address	**City**	**State**	**Zip**
University Park	Los Angeles	CA	90089
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
The Morgan School		9/66-6/69	
Address	**City**	**State**	**Zip**
Killingworth Turnpike	Clinton	CT	06413
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24-present	[redacted]	Las Vegas	NV	89138
6/23-4/24		Las Vegas	NV	89149
5/20-6/23		Henderson	NV	89052
6/12-5/20		Henderson	NV	89012
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Allivet			7/22-present	
Business Address		**City**	**State**	**Zip**
3250 W. Ali Baba Lane		Las Vegas	NV	89118
Phone	**Title**		**Number of Employed Hours**	
888-320-1374	Pharmacist in Charge		4720	
Description of Duties				
Staff pharmacist tasks, verification and dispensing of prescriptions via mail order, in addition to PIC responsibilities				

Business Name			From - To (MM/YY – MM/YY)	
Chewy			1/21-3/22	
Business Address		**City**	**State**	**Zip**
255 S. 143rd Avenue		Goodyear	AZ	85338
Phone	**Title**		**Number of Employed Hours**	
800-672-4399	Staff Pharmacist		2240	
Description of Duties				
Staff pharmacist tasks, verification and dispensing of prescriptions via mail order				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Christopher Tarangul, **certify that as the designated representative for**

Agropec Trading, LLC dba Allivet,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CT I am at least 21 years of age;
3. CT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Tarangul

Print Name (First, Last)

Chr Tar

Original Signature (electronic, copies or stamps not accepted)

11/20/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Tarangul

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/24

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, CHRISTOPHER TARANGUL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/24

Date

Subscribed and Sworn to before me this 20TH day of NOVEMBER 2024.

Notary Public Signature

MAYLENE DELOS SANTOS
Notary Public, State of Nevada
Appointment No. 22-3106-01
My Appt. Expires May 6, 2026

(Seal)

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: Applying For
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: OptumRx Pharmacy of Nevada, Inc., d/b/a Culinary Pharmacy

Physical Address: 960 W. Craig Road

City: North Las Vegas State: NV Zip: 89032

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (725) 332-6464 Toll Free # (NAC 639.708, NRS 639.23286): None

Fax: (752) 332-6454 Contact Email: orxpharmlic@optum.com

Website: _____

Nevada Business License # (if applicable) NV19961247896

Supervising/Managing Pharmacist Name (NRS 639.220): Vivian Ho

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20251

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Vivian Ho	NV Pharmacist Registration #: 20251
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: None	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): OptumRx Health Solutions, LLC

Corporation/Organization Name: OptumRx Pharmacy of Nevada, Inc.

Mailing Address: 960 W. Craig Road

City: North Las Vegas State: NV Zip: 89032

Telephone: (888) 445-8745 Email: orxpharmlic@optum.com

Contact Person Name: Christine Feldman

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for OptumRx Pharmacy of Nevada, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Kevin Burr

Print Name of Authorized Person

Kevin E. Burr

Original signature of Authorized Person (copies or stamps not accepted)

11-18-2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Vivian ho hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for OptumRx Pharmacy of Nevada, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of November, 2024

Mandip Kaur
Notary Public

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
February 20, 2027
No. 23-7466-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Vivian Ho Pharmacist Registration #: 20251

Pharmacy Name: OptumRx Pharmacy of Nevada, Inc.

Initial each statement below to indicate you have read and agree with the following:

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

11/19/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Burr

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kevin E Burr — 11-18-2024

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 11/26/24	Amount: $500 ck 1534660 34

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **OPTUMRX PHARMACY OF NEVADA, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/19/1996, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/14/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202411145185856
You may verify this certificate online at https://www.nvsilverflume.gov/home

Optum Rx®

LIST OF OFFICERS AND DIRECTORS

OptumRx Pharmacy of Nevada, Inc.
d/b/a Culinary Pharmacy
960 W. Craig Road
North Las Vegas NV 89032

Name	Title	Address	Ownership Interest
Kathryn Eve Carey	Director	1 Optum Circle, Suite 100 Eden Prairie MN 55344	0%
Erin Ann Satterwhite	Director, President & CEO	1 Optum Circle, Suite 100 Eden Prairie MN 55344	0%
Marilyn Victoria Hirsch	Treasurer	1 Optum Circle, Suite 100 Eden Prairie MN 55344	0%
Kevin Eugene Burr	Secretary	1 Optum Circle, Suite 100 Eden Prairie MN 55344	0%
Heather Anastasia Lang	Assistant Secretary	1 Optum Circle, Suite 100 Eden Prairie MN 55344	0%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: OptumRx Pharmacy of Nevada, Inc., d/b/a Culinary Pharmacy

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 960 W. Craig Road

City: North Las Vegas State: NV Zip: 89032

Mailing Address (if different from physical address): same as physical

City: State: Zip:

Telephone: (752) 332-6464 Website:

Licensing Company Email: orxpharmlic@optum.com

Section 2: Personal Information

First: Vivian Middle: Wai Yin Last: Ho

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: 89113

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences - college of Pharmacy		8/16 - 5/19	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any	Doctorate of Pharmacy (Pharm.D)		

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las vegas		8/13 - 5/16	
Address	**City**	**State**	**Zip**
4505 S. Maryland Pkwy.	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Northwest Career and Technical Academy		8/09 - 5/13	
Address	**City**	**State**	**Zip**
8200 W. Tropical Pkwy	Las Vegas	NV	89149
Diploma/Degree obtained, if any	High School Diploma		

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/23 - current	[redacted]	Las Vegas	NV	89113
6/20 - 6/23	[redacted]	Las vegas	NV	89113
5/18 - 6/20	[redacted]	Las Vegas	NV	89113
8/16 - 5/18	[redacted]	Henderson	NV	89014
8/06 - 8/16	[redacted]	N. Las Vegas	NV	89081

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Optum Infusion Pharmacy			1/23 - 12/24	
Business Address	**City**		**State**	**Zip**
8655 S. Eastern Ave.	Las Vegas		NV	89123
Phone	**Title**		**Number of Employed Hours**	
855-855-8754	Clinical Infusion Pharmacist		3500	
Description of Duties				
verify prescription orders, clarify prescriptions reciered, manage inventory of medications, counsel patients on incoming orders				

Business Name			From - To (MM/YY – MM/YY)	
Capsule Pharmacy			7/21 - 12/22	
Business Address	**City**		**State**	**Zip**
801 S. Rancho Dr.	Las Vegas		NV	89106
Phone	**Title**		**Number of Employed Hours**	
888-910-1808	Pharmacist in Charge		2500	
Description of Duties				
dispense prescription orders, verify prescription orders, triage insurance issues, deliver medications, counsel on prescriptions, inventory management, recordkeeping				

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy			8-19 to 7/21	
Business Address	**City**		**State**	**Zip**
1600 N. Buffalo Dr.	Las Vegas		NV	89128
Phone	**Title**		**Number of Employed Hours**	
7028045511	Pharmacy Manager		3500	
Description of Duties				
controlled substance inventory management, dispensing of medications, prescription verification, counseling on prescriptions, inventory control, clinical interventions				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Vivian Ho, **certify that as the designated representative for**

OptumRx Pharmacy of Nevada, Inc., d/b/a Culinary Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AAA I am at least 21 years of age;
3. AAA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AAA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AAA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AAA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AAA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vivian Ho

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vivian Ho

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Vivian Ho, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/21/24

Date

Subscribed and Sworn to before me this 21 day of Nov. 2024.
by vivian waiyin Ho

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
XIANG AO
My Appointment Expires
February 27, 2028
No. 16-2659-1

(Seal)

Optum

November 25, 2024

To: Nevada State Board of Pharmacy
985 Diamonte Ranch Parkway, # 206
Reno, NV 89521

Re: OptumRx Pharmacy of Nevada, Inc., d/b/a Culinary Pharmacy
960 W. Craig Road
North Las Vegas, NV 89032
Nevada Pharmacy License – Applying For

Please accept this letter as formal notice that Vivian Ho, in her capacity as Pharmacist-In-Charge of the above-mentioned pharmacy, is an authorized person to speak on behalf of OptumRx Pharmacy of Nevada, Inc., d/b/a Culinary Pharmacy.

Please let us know if you have any additional questions.

Thank you,

Kevin E. Burr

Kevin Burr, Secretary

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Aequita Pharmacy

Physical Address: 12825 NE 126th Pl

City: Kirkland State: WA Zip: 98034-7721

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 425-224-2330 Toll Free # (NAC 639.708, NRS 639.23286): 844-282-1430

Fax: 425-305-4175 Contact Email: nate@aequitapharmacy.com

Website: www.aequitapharmacy.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Nathan Kenney

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~n/a~~ 24264

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nathan Kenney (manager/PIC)	NV Pharmacist Registration #: ~~n/a~~ 24264
Name: Thomas Chen (staff pharmacist)	NV Pharmacist Registration #: n/a
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Nathan Kenney

Business Name: Aequita Pharmacy

Business Address: 12825 NE 126th Pl

City: Kirkland State: WA Zip: 98034-7721

Telephone: 425-224-2330 Email: nate@aequitapharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/President/PIC (title) for Aequita Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Nathan Kenney

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/18/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Kenney

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/18/24

Date

Board Use Only	Date Received: 4/23/24	Amount: $500-cc

UNITED STATES OF AMERICA

The State of Washington

Secretary of State

I, STEVE R. HOBBS, Secretary of State of the State of Washington and custodian of its seal, hereby issue this

CERTIFICATE OF EXISTENCE

OF

AEQUITA PHARMACY LLC

I CERTIFY that the records on file in this office show that the above named entity was formed under the laws of the State of Washington and that its public organic record was filed in Washington and became effective on 05/09/2023.

I FURTHER CERTIFY that the entity's duration is Perpetual, and that as of the date of this certificate, the records of the Secretary of State do not reflect that this entity has been dissolved.

I FURTHER CERTIFY that all fees, interest, and penalties owed and collected through the Secretary of State have been paid.

I FURTHER CERTIFY that the most recent annual report has been delivered to the Secretary of State for filing and that proceedings for administrative dissolution are not pending.

Issued Date: 03/18/2024
UBI Number: 605 242 533

Given under my hand and the Seal of the State of Washington at Olympia, the State Capital

Steve R. Hobbs, Secretary of State

Date Issued: 03/18/2024

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

April 15, 2024

Utah Board of Pharmacy

Subject: License Verification

To Whom It May Concern:

This verifies the status of the PHAR - for Aequita Pharmacy.

You may see blank sections because we do not have the information in our database or it does not apply for this credential type. This information is valid from the date of this letter.

Credential Number:	PHAR.CF.61458335
Current Credential Status:	ACTIVE
First Issuance Date:	03/25/2024
Current Expiration Date:	05/31/2025
Last Renewal Date:	03/25/2024
Disciplinary Action:	No

Please call 360-236-4700 if you have questions, or check our Online Facility Search at: https://fortress.wa.gov/doh/facilitysearch/. Information on current facility-specific rules and laws is at https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate.

Julie Owen

Julie A Owen, HSC1

Washington State Department of HEALTH

Facility Search

Search

Search

Facility Information

NEW SEARCH | RESULTS

Facility Name: Aequita Pharmacy
Address: 12825 NE 126th Pl, Kirkland, WA, 98034-7721
Owner's Name: Aequita Pharmacy LLC
License #: PHAR.CF.61458335
Facility Status: ACTIVE
Facility Type: Pharmacy License
License Expires On: 05/31/2025

If you find any errors in this description, please complete the Feedback form and send it to us.

Washington State Department of Health

This organization

Acquita Pharmacy

is authorized by RCW 18.64 to have a

Pharmacy License

To Provide

Ancillary Utilization

Operated by: Acquita Pharmacy LLC

Pharmacy Type: Mail Order

Located at: 12825 NE 128th Pl
Kirkland, WA 98034-7721

Secretary

Status
ACTIVE

Credential Number
PHAR.CF.61458335

Effective Date
03/25/2024

Expiration Date
04/01/2026

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47852 • Olympia, Washington 98504-7852
Tel: 360-236-4946 • 711 Washington Relay Service

March 19, 2024

Nathan Robert Kenney
Aequita Pharmacy
12825 NE 126th Pl Ste B465
Kirkland, WA, 98034-7721

Delivered via email to: *Nate Kenney nate@aequitapharmacy.com*

Subject: Inspection Number: X2023-551
Facility Type: Mail Order
License Number: PHAR.CF.61458335
Inspection Type: NEW LICENSURE - INITIAL

Dear Nathan Robert Kenney,

This letter contains information regarding the recent inspection of Aequita Pharmacy, 12825 NE 126th Pl Ste B465, Kirkland, WA, 98034-7721 by the Washington State Department of Health. Your state licensing inspection was completed on 02/26/2024. Inspections represent the scope of practice observed during the inspector's time on-site and may not be all inclusive.

During the initial licensing inspection process, the licensee met minimum required expectations for licensure.

Please contact me if there are questions regarding the inspection process. You may reach me at (360) 485-5088. I am also available by email at Mariam.Boulos@doh.wa.gov.

Sincerely,

Mariam Boulos

Mariam Boulos BS Pharm
Pharmacist Inspector

How was your pharmacy inspection experience?

Please take a few minutes to complete this brief survey. In order to provide you with the best possible service, we need your comments on how we do our job, especially if you can offer suggestions for improvement. Unless you choose to give us your contact information, this is an anonymous survey. The survey is voluntary and will not affect your current or future inspection results. All responses will be used solely to improve our pharmacy inspection service.

https://fortress.wa.gov/doh/opinio/s?s=PharmacyInspectionSurvey

Washington State Pharmacy Quality Assurance Commission

Telephone Contact Numbers

Marlee B. O'Neill, Executive Director	360-480-9108
Lindsay Trant-Sinclair, Deputy Director	564-999-3341
Si Bui, PharmD, MPH, Inspection Supervisor	360-791-4301
T. Nomi Peaks, PharmD, Pharmacy Consultant	360-236-4988
Facsimile	360-236-2260

Websites

Washington State Pharmacy Quality Assurance Commission	www.doh.wa.gov/pharmacy
Washington Pharmacy Quality Assurance Commission (email)	WSPQAC@doh.wa.gov
Drug Enforcement Administration (DEA)	www.deadiversion.usdoj.gov
Food & Drug Administration (FDA)	www.fda.gov/cder
Consumer Product Safety Commission	www.cpsc.gov
U.S. Pharmacopeia (USP)	www.usp.org

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Aequita Pharmacy

Pharmacy/Wholesaler License # (if applicable) PHAR.CF.61458335

Physical Address 12825 NE 126th Pl.

City Kirkland State WA Zip 98034

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 425-224-2330 Website www.aequitapharmacy.com

Licensing Company Email nate@aequitapharmacy.com

Section 2: Personal Information

First Nathan Middle Robert Last Kenney

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]

City Shoreline State WA Zip 98133

Telephone[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Washington School of Pharmacy		09/07-03/12	
Address	**City**	**State**	**Zip**
1959 NE Pacific St	Seattle	WA	98125
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Washington		09/03-06/07	
Address	**City**	**State**	**Zip**
1959 NE Pacific St	Seattle	WA	98125
Diploma/Degree obtained, if any			
Bachelor of Science - Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Liberty High School		09/99-06/03	
Address	**City**	**State**	**Zip**
16655 SE 136th St.	Renton	WA	98059
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/18-current	[redacted]	Shoreline	WA	98133
03/14-08/18	[redacted]	Seattle	WA	98125

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Aequita Pharmacy			05/23-current
Business Address	**City**	**State**	**Zip**
12825 NE 126th Pl	Kirkland	WA	98034
Phone	**Title**		**Number of Employed Hours**
425-224-2330	Director of Pharmacy, pharmacist in charge		1,740
Description of Duties			
Pharmacy management, financial oversight, pharmacist duties such as verifying prescriptions and counseling patients			

Business Name			From - To (MM/YY – MM/YY)
Lexar Corporation			04/12-04/23
Business Address	**City**	**State**	**Zip**
1536 N 115th St. Suite 100	Seattle	WA	98133
Phone	**Title**		**Number of Employed Hours**
206-365-2255	Director of Pharmacy		22,968
Description of Duties			
Pharmacy management, financial oversight, pharmacist duties such as verifying prescriptions and counseling patients			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Nathan Kenney **, certify that as the designated representative for**

Aequita Pharmacy ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. y I am at least 21 years of age;
3. y I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. y I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. y I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. y I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. y I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nathan Kenney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/19/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Kenney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of Snohomish

I, Nathan Kenney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/19/24

Date

Subscribed and Sworn to before me this 19th day of March 2024

Cecilia Locsin

Notary Public Signature

CECILIA LOCSIN
Commission #30430
NOTARY PUBLIC
Exp 08-04-2026
STATE OF WASHINGTON
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Aequita Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PHAR.CF.61458335 (WA)

Physical Address: 12825 NE 126th Pl

City: Kirkland State: WA Zip: 98034

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 425-224-2330 Website: www.aequitapharmacy.com

Licensing Company Email: nate@aequitapharmacy.com

Section 2: Personal Information

First: Nathan Middle: Robert Last: Kenney

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Shoreline State: WA Zip: 98133

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Washington School of Pharmacy		09/07-03/12	
Address	**City**	**State**	**Zip**
1959 NE Pacific St	Seattle	WA	98125
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Washington		09/03-06/07	
Address	**City**	**State**	**Zip**
1959 NE Pacific St	Seattle	WA	98125
Diploma/Degree obtained, if any			
Bachelor of Science - Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Liberty High School		09/99-06/03	
Address	**City**	**State**	**Zip**
16655 SE 136th St	Renton	WA	98059
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/18-current	[redacted]	Shoreline	WA	98133
03/14-08/18	[redacted]	Seattle	WA	98125

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Aequita Pharmacy			05/23-current	
Business Address		**City**	**State**	**Zip**
12825 NE 126th Pl.		Kirkland	WA	98034
Phone	**Title**			
425-224-2330	Director of Pharmacy, pharmacist in charge			
Description of Duties				
Pharmacy management, financial oversight, pharmacist duties such as verifying prescriptions and counseling patients				

Business Name			From - To (MM/YY – MM/YY)	
Lexar Corporation			04/12-04/23	
Business Address		**City**	**State**	**Zip**
1536 N 115th St. Suite 100		Seattle	WA	98133
Phone	**Title**			
206-365-2255	Director of Pharmacy			
Description of Duties				
Pharmacy management, financial oversight, pharmacist duties such as verifying prescriptions and counseling patients				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Kenney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of Snohomish

I, Nathan Kenney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/19/24

Date

Subscribed and Sworn to before me this 19th day of March 2024

Notary Public Signature

CECILIA LOCSIN
Commission #30430
NOTARY PUBLIC
Exp. 08-04-2026
STATE OF WASHINGTON
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Aequita Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 12825 NE 126th Pl.

City: Kirkland State: WA Zip: 98034

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 425-224-2330 Toll Free # (NAC 639.708, NRS 639.23286): 844-282-1430

Fax: 425-305-4175 Contact Email: nate@aequitapharmacy.com

Website: www.aequitapharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Nathan Kenney

Supervising/Managing Pharmacist NV Pharmacist Registration #: n/a, no NV license. WA license # PH60287806

Name of Person with direct knowledge of compounding procedures: Nathan Kenney

Email of Person with direct knowledge of compounding procedures: nate@aequitapharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 425-260-0045

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
tirzepatide/niacinamide injectable solution
semaglutide/cyanocobalamin injectable solution
methylcobalamin
Trimix/Bimix
glutathione

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: ARL Bio Pharma

Address: 80 Research Parkway Suite 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

7. What is your procedure for visual inspection of compounded sterile products?

Physical testing requirements:The end product must be visually inspected for: Container leaks, integrity, solution cloudiness or phase separation, appropriate color and volume separation

Particulate testing (liquids):
Sampling (one unit per batch and, if placed in storage, immediately before shipping).
Wipe the container with a damp, lint-free wipe to remove any external particles.
Using powder-free gloves, hold the container by its top and swirl the contents by rotating the wrist in a circular motion.
Hold the container horizontally about four inches below a light source against a white and/or black background and move the container back and forth.

8. How often do you perform glove fingertip and medial fill testing?

Every 3 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Immediate re-training including in person coaching and review of any potential contributiing issues, as well as review of training modules, followed by a re-test of competency.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Our staff annually review the 28 modules in CriticalPoint©s USP 797 course, as well as completion of on-site/in-person review of all USP 797 competencies in our Simplifi 797/SoleSource portal. These include garbing and gowning, gloved fingertip testing, and media fill testing.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Weekly full cleaning of PECs and SEC are completed using PreEmpt RTU as disinfectant, followed by Peridox RTU as sporicidal agent, follwed by sterile isopropyl alcohol as cleaning agent.

12. Who performs the sterile compounding process at your facility?

Only pharmacists and technicians that are trained in our sterile compounding processes.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The pharmacist in charge and staff pharmacists.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

If medications require refrigeration, they are shipped with freezer packs and/or ice rods to keep them at the desired temperature, inside a styrofoam-lined cooler box if needed depending on time of year and weather conditions in the place we are shipping to. They are also padded to avoid excessive shaking and labeled as fragile.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
tirzepatide/niacinamide injectable solution
semaglutide/cyanocobalamin injectable solution
methylcobalamin
Trimix/Bimix
Glutathione

2. What sterilization methods are utilized at your facility?
Sterilization by filtration. Sterilization is tested and validated by a third party lab on each compound.

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:
n/a

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Kenney
Name of Person who Completed the Form

Pharmacist in charge
Title

Signature (copies or stamps not accepted)

4/16/24
Date

Board Use Only	Date Received: 4/23/24 Date Approved: _____ Approved By: _____

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FB3417602
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 02247		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Kroger Specialty Infusion CA

Physical Address: 19110 Van Ness Ave.

City: Torrance State: CA Zip: 90501

Mailing Address (if different from physical address): PO Box 162088

City: Altamonte Springs State: FL Zip: 32716

Telephone: 310-320-6444 Toll Free # (NAC 639.708, NRS 639.23286): 866-202-9552

Fax: 866-794-4844 Contact Email: license@bioplusrx.com

Website: www.bioplusrx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Gilberto Melo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kirankumar Kanaiyalal Patel	NV Pharmacist Registration #: 21368
Name: Lucia Maria Riva	NV Pharmacist Registration #: 12381
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Kroger Specialty Infusion Holdings, Inc.

Corporation/Organization Name: Kroger Specialty Infusion CA, LLC

Mailing Address: 19110 Van Ness Ave.

City: Torrance State: CA Zip: 90501

Telephone: 310-320-6444 Email: license@bioplusrx.com

Contact Person Name: Kimberly Bourcier

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Kroger Specialty Infusion CA (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Danielle Swenson

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

8/6/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Danielle Swenson

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/6/24

Date

Board Use Only	Date Received: 9/3/24	Amount: $500-CK 1000001681

Kroger Specialty Infusion CA

Discipline Statement

On 8/3/21, the Texas State BOP issued KSI CA an administrative penalty for operating without a licensed Texas Pharmacist-in-Charge. KSI CA paid a $1000 fine. Documentation is attached.

In 2018, the Alabama BOP issued a Deferral Agreement with a $1,000; this agreement was not regarded as disciplinary action and had no impact on the pharmacy's license. Documentation is attached.

Under the previous ModernHealth ownership, the pharmacy was placed on probation by the Ohio, Oregon, Hawaii, and Texas Boards of Pharmacy.

- The OH BOP issued the probation in 2014 and terminated probation as a result of the change of ownership in 2017.
- The OR BOP issued probation in 2015, completed in 2016.
- The HI BOP issued a one-year probation and $2,500 fine in 2015.
- The TX BOP issued a two-year probation and $1,200 fine in 2015. All probation statuses have since been resolved.

TEXAS STATE BOARD OF PHARMACY

August 10, 2021

KROGER SPECIALTY INFUSION CA
C/O KIRANKUMAR KANAIYALAL PATEL
PHARMACIST-IN-CHARGE
19110 VAN NESS AVE
TORRANCE CA 90501

RE: In the Matter of Kroger Specialty Infusion CA

Dear Kirankumar Kanaiyalal Patel:

Enclosed is a copy of Agreed Board Order (ABO) #2020-02929 that was entered by the Texas State Board of Pharmacy (Board) concerning the above-referenced matter. The Board entered this Order on August 3, 2021. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Kroger Specialty Infusion CA (pharmacy license #31361) must pay an administrative penalty (fine) of $1,000.00. **This fine is due on or before December 1, 2021.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the Board's office by the due date. Please include your ABO number (#2020-02929) on the cashier's check or money order. **Note:** The Board will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

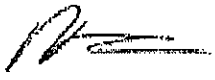
Prior to the next expiration date of pharmacy license #31361, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the PHARMACY, THE PHARMACY'S owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #2020-02929, Kroger Specialty Infusion CA must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, a Kroger Specialty Infusion CA representative must answer "yes" to this question on any renewal applications submitted beginning August 3, 2021 and ending 36 months following the termination of all sanctions.

If you have any questions about this Order, please contact Madeline Fojtik, Enforcement Specialist, at (512) 305-8054 or via madeline.fojtik@pharmacy.texas.gov.

Sincerely,



Robert Rivera
Enforcement Program Manager

RR:mf

Enclosure: Agreed Board Order #2020-02929

c: Kroger Specialty Infusion CA, LLC
Christine Wheatley, Managing Officer
19110 Van Ness Avenue
Torrance, California 90501

AGREED BOARD ORDER #2020-02929

RE: IN THE MATTER OF KROGER SPECIALTY INFUSION CA (PHARMACY LICENSE #31361)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 31361 issued to Kroger Specialty Infusion CA (Respondent), 19110 Van Ness Avenue, Torrance, California 90501.

By letter dated May 18, 2021, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2019); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2020), in that allegedly:

COUNT

On or about January 24, 2020, through on or about June 21, 2020, Kroger Specialty Infusion CA, 19110 Van Ness Avenue, Torrance, California 90501, was engaged in the operation of a non-resident pharmacy engaged in compounding sterile preparations in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated May 18, 2021, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Christine Wheatley, Managing Officer, Kroger Specialty Infusion CA, LLC on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2019), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2021).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 3rd day of August, 2021.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Christine Wheatley, Managing Officer, Kroger Specialty Infusion CA, LLC
On behalf of Kroger Specialty Infusion CA

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

Kroger Specialty Infusion CA	Vendor ID	Vendor	Date	Check Number
	41TEX003	TEXAS STATE BOARD OF PHARMACY	06/01/2021	006668

Invoice Number	Invoice Date	Gross Check Amt	Discount Taken	Net Check Amt
ADMIN PENALTY	05/26/2021	$1,000.00	$0.00	$1,000.00
TOTALS:		$1,000.00	$0.00	$1,000.00

THIS DOCUMENT IS PROTECTED BY INVISIBLE FIBERS AND CHEMICALLY REACTIVE PAPER. HOLD TO LIGHT TO VERIFY A TRUE WATERMARK

Kroger Specialty Infusion CA
3200 Lake Emma Rd.
Lake Mary, FL 32746

BB&T
BRANCH BANKING AND TRUST COMPANY
NORTH CAROLINA
66-112/531

Jun 1, 2021 (DATE) | 006668 (CHECK NO.)

AMOUNT
$1,000.00

Pay One Thousand Dollars And 00 Cents

FAVORS. DETACH ON BACK

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
KROGER SPECIALTY INFUSION CA f/k/a BIOFUSION, LLC	)	
	)	
	)	
Non-Resident Pharmacy Permit Number: 114160	)	**CASE NO: 16-L-0132**
	)	

DEFERRAL AGREEMENT

This Agreement is entered into by and between the Alabama State Board of Pharmacy (Board) and Kroger Specialty Infusion CA f/k/a Biofusion, LLC (Kroger).

WHEREAS, Kroger was timely served with a Statement of Charges and Notice of Hearing (Pending Charges) alleging violations of the Alabama Pharmacy Practice Act. A copy of the Pending Charges is attached hereto as Exhibit "A".

WHEREAS, the parties, through counsel, have engaged in discussions concerning an informal resolution of the Pending Charges.

WHEREAS, the parties have agreed to resolve this matter pursuant to Code of Alabama (1975) 41-22-12(f) by their approval of the following terms:

IT IS THE THEREFORE UNDERSTOOD AND AGREED BY THE PARTIES AS FOLLOWS:

1. The Pending Charges against Kroger shall be deferred until December 31, 2018.

2. As a condition to the deferral described above, Kroger shall pay costs in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Agreement, that being the date it is signed on behalf of the Board. Failure to pay this amount shall be considered a probable cause violation by Kroger as defined below.

3. In the event there are no probable cause violations of the Alabama

Pharmacy Practice Act involving Kroger during the deferral period set forth above, the Pending Charges shall be dismissed. Discipline in another state based upon the Ohio Order the subject of the Pending Charges shall not be considered a probable cause violation.

4. In the event there is a probable cause violation of the Alabama Pharmacy Practice Act involving Kroger during the deferral period set forth above, both the Pending Charges and any new charges shall be noticed and scheduled for a hearing.

5. Neither the Pending Charges or this Agreement shall be reported as discipline as long as Kroger complies with the conditions of Paragraphs Two through Four of this Agreement.

DONE this the 13 day of Feb, 201__.

James S. Ward
Ward & Cooper, LLC
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209

David Darby, R.Ph.
President, Alabama State
Board of Pharmacy

DONE this the 11th day of January, 2018.

Kroger Specialty Infusion CA f/k/a
Biofusion, LLC

By: _____
Its: Vice President & Secretary

Jim Hoover, Attorney for Kroger
Specialty Infusion CA f/k/a
Biofusion, LLC

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	BEFORE THE ALABAMA STATE
KROGER SPECIALTY INFUSION CA f/k/a BIOFUSION, LLC	)	BOARD OF PHARMACY
	)	
Non-Resident Pharmacy Permit Number: 114160	)	CASE NO: 16-L-0132
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Kroger Specialty Infusion CA**
f/k/a BioFusion, LLC
19110 Van Ness Avenue
Torrance, California 90501

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____ _____, 2018 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Kroger Specialty Infusion CA f/k/a BioFusion, LLC (Kroger) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Kroger has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon an Order entered by the Ohio State Board of Pharmacy on February 7, 2014 attached hereto as Exhibit "A" resulting in your license as a Terminal Distributor of Dangerous Drugs being placed

on probation for a period of five (5) years subject to your compliance with the terms set out in the above referenced Order.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) based upon the Agreed Board Order issued by the Texas State Board of Pharmacy on November 3, 2015 attached hereto as Exhibit "B" resulting in your license being placed on probation for two (2) years subject to your compliance with the terms set out in the above referenced Order.

COUNT FOUR

Violating Code of Alabama (1975), § 34-23-33(13) based upon the entry of a Consent Order by the Oregon State Board of Pharmacy as set out in Paragraph 5 on the Uncontested Facts in a Settlement Agreement entered by the Hawaii State Board of Pharmacy on April 6, 2016 attached hereto as Exhibit "C".

COUNT FIVE

Violating Code of Alabama (1975), § 34-23-33(13) based upon the entry of the discipline by the Hawaii State Board of Pharmacy referenced above.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture,

dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT SIX

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2017.

ALABAMA STATE BOARD OF PHARMACY

_____

By: Susan Alverson
Secretary

EXHIBIT A

OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126
-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143 *E-MAIL:* exec@bop.state.oh.us *FAX:* 614/752-4836
TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750 *URL:* http://www.pharmacy.ohio.gov

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy
Kyle W. Perkins, Executive Director
Date: 2-7-14
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2013-1421)

In The Matter Of:

BIOFUSION, LLC
c/o SHERRI CHERMAN, R.Ph.
1910 Van Ness Ave.
Torrance, CA 9501

INTRODUCTION

The Matter of Biofusion, LLC came for hearing on January 7, 2014, before the following members of the Board: Kevin J. Mitchell, R.Ph.; (presiding); Edward T. Cain, Public Member; Melinda J. Ferris, R.Ph.; Margaret A. Huwer, R.Ph.; Megan E. Marchal, R.Ph.; Michael A. Moné, R.Ph.; and Kilee S. Yarosh, R.Ph.

Richard F. Kolezynski, R.Ph., Absent.

Biofusion, LLC was not present and Biofusion, LLC. is represented by Stacie K. Neroni, who also was not present. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. Sheri Zapadka, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Copy of Proposal to Deny/Notice of Opportunity for hearing letter	[10-15-13]
1A-1C.	Procedurals	
2.	Correspondence from Staci K. Neroni; Application for Out of State Terminal Distributor of Dangerous Drugs License	[04-19-13]

Respondent's Exhibits:

A.	Contentions	[11-14-13]

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

(1) Records of the Board of Pharmacy indicate that on or about April 2, 2013, Sherri Cherman was the President of Biofusion, 19110 Van Ness Ave., Torrance, California and that on said date, Biofusion submitted an application for registration as a Terminal Distributor of Dangerous Drugs.

(2) On or around October 10, 2011, Modern Healthcare, Inc. D.B.A AD-Rx Pharmacy entered into a Stipulated Settlement and Disciplinary Order with the California State Board of Pharmacy concerning the loss of approximately 470,000 tablets of hydrocodone/APAP 10/325 mg tablets due to employee pilferage. In the Matter of the Accusation Against: Modern Healthcare, Inc., d.b.a., AD-Rx Pharmacy and Robert Antoine Charles, Case No. 3539. Modern Healthcare, Inc. is listed as an owner of Biofusion, the applicant. Such conduct, if proven, constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

(3) The applicant has failed to furnish satisfactory proof to the Board that adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs as required by Ohio Revised Code Section 4729.55(C). To wit: another pharmacy owned by the same company did, on or before May 17, 2012, experience significant loss of controlled substances. Such loss was attributable to the actions of a pharmacy employees and poor recordkeeping. Such conditions violate, or allow the violation of Section 4729.55 of the Ohio Revised Code, and constitute a failure to meet the qualifications for a Terminal Distributor of Dangerous Drugs.

DECISION OF THE BOARD

Pursuant to Section 4729.11 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the Application for Registration as a terminal Distributor of Dangerous Drugs submitted by Biofusion, L.L.C. on or about April 2, 2013.

Further, State Board of Pharmacy hereby places on probation for a period of five years the Terminal Distributor License, issued to Biofusion, LLC effective as of the date the license becomes active. The terms of probation are as follows:

(A) Biofusion, L.L.C. must submit to this Board annual reports of any theft or loss of drugs during the period of probation.

(B) Biofusion, LLC must not violate the drug laws of Ohio, any other state, or the federal government.

(C) Biofusion, LLC must abide by the rules of the State Board of Pharmacy.

(D) Biofusion, LLC must comply with the terms of this Order.

(E) Biofusion, LLC's license is deemed to be not in good standing until successful completion of the probationary period.

(F) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Biofusion, LLC is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

Margaret Huwer moved for Findings of Fact; Megan Marchal seconded the motion. Motion passed (Aye-6/Nay-0).

Megan Marchal moved for Action of the Board; Michael Moné seconded the motion. Motion passed (Aye-5/Nay-1).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

Section 119.12 of the Ohio Revised Code authorizes an appeal from this Order. An order that denied admission to an examination, or denied the issuance or renewal of a license or registration, or revoked or suspended a license, may be appealed to the court of common pleas in the Ohio county of your place of business or in your Ohio county of residence. Any other order may be appealed to the Court of Common Pleas of Franklin County, Ohio.

Such an appeal, setting forth the order appealed from and the grounds of the appeal, must be commenced by the filing of the ORIGINAL Notice of Appeal with the State Board of Pharmacy and a copy with the appropriate court within fifteen (15) days after the mailing of this Order and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: 2-7-14

By: _____
Kyle W. Parker, M.B.A., R.Ph., Executive Director

KWP/ljp
Certified Mail / Return Receipt
7004 1160 0000 5912 7454
c: Charissa D. Payer, Assistant Attorney General
Stacie K. Neroni, Esq.

EXHIBIT B

AGREED BOARD ORDER #L-15-003

RE: IN THE MATTER OF BIOFUSION (PHARMACY LICENSE #27196)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 27196 issued to Biofusion (Respondent), 19110 Van Ness Avenue, Torrance, California 90501.

By letter dated July 13, 2015, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(9) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013), as alleged in the Count below.

The conduct described in the Order of the Ohio State Board of Pharmacy is substantially similar to conduct described in:

> Section 565.002(a)(9) and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3; Subtitle J (2013); and
>
> Section 291.32(b)(2) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

COUNT

On or about February 7, 2014, the Ohio State Board of Pharmacy entered an Order against the application for registration as a terminal distributor of dangerous drugs of Biofusion, LLC. The Order was based on findings of fact that a listed owner of Biofusion, LLC (i.e., Modern Healthcare, Inc., d.b.a. AD-RX Pharmacy) had been subject to a Settlement and Disciplinary Order entered by the California Board of Pharmacy on October 10, 2011, for employee diversion of approximately 470,000 tablets of hydrocodone/APAP 10/325 mg tablets. Based on this finding, the Ohio State Board of Pharmacy determined Biofusion, LLC failed to furnish proof of adequate safeguards to prevent the sale or other distribution of dangerous drugs in an unauthorized manner. The Order granted the registration subject to a five-year probation.

An informal conference was held in the Board's office on September 2, 2015, with James Markis, Pharm.D., Director of Pharmacy, Biofusion; Michael R. Hess, General Counsel, Biofusion; Joan Schuckenbrock, Chief Administrative Officer, Modern Health, on behalf of Respondent; and Nanette K. Beaird, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggoner, R.Ph., Board

Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Caroline Hotchkiss, Assistant General Counsel. Ginger Shuffler, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Joan Schuckenbrock and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent's license shall be placed on probation for a period of two (2) years, with such period to commence thirty (30) days after the entry of this Order. During the period of probation, Respondent shall abide by the terms of this Order, and shall not violate any pharmacy or drug statute or rule of this state, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs.

(2) Respondent shall pay a probation fee of one thousand two hundred dollars ($1,200) due one hundred twenty (120) days after the entry of this Order.

(3) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 3rd day of November, 2015.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Joan Schuckenbrock, Chief Administrative Officer, Modern Health
For and on behalf of Biofusion

Nanette K. Beaird, Legal Counsel for Biofusion
Gardere, Wynne, Sewell, LLP
600 Congress Avenue, Suite 3000
Austin, Texas 78701

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\PNLs 0115 - 1215\Biofusion\Biofusion_ABO_281601.docx

OCT

EXHIBIT C

2016 A[illegible] 9:56

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2016 APR 28 P 2:25
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	)	PHA 2015-134-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" THROUGH "3"

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent BIOFUSION, LLC (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under permit number PMP 908. The permit was issued on or about January 1, 2014. The permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is 19110 Van Ness Avenue, Torrance, California 90501.

3. RICO received a request for investigation from the Board of Pharmacy after Respondent reported disciplinary actions on a December 2, 2015 renewal application.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

4. Respondent attached a copy of an Order issued to Respondent by the Ohio State Board of Pharmacy in Case Number 2013-1421 (hereinafter "the Ohio Order") (Exhibit "1"). The Ohio Order was based on disciplinary action taken by the State of California against Respondent's corporate owner (also a permitted pharmacist), alleging failure to account for medications due to employee pilferage. Respondent's Ohio permit was placed on probation for five years with conditions.

5. Respondent also attached a copy of a Consent Order issued to Respondent by the Oregon Board of Pharmacy in Case No. 2015-0142 (hereinafter "the Oregon Order") (Exhibit "2"). The Oregon Order was also based on the California action against Respondent's corporate owner and imposed probation with conditions.

6. Respondent also attached a copy of Agreed Board Order #L-15-003 issued to Respondent by the Texas State Board of Pharmacy in Agreed Board Order #L-15-003 (hereinafter "the Texas Order") (Exhibit "3"). The Texas Order was also based on the California action against Respondent's corporate owner and imposed probation, with conditions, including a $1,200.00 probation fee.

7. RICO alleges that disciplinary action was taken against Respondent by the States of California, Oregon, and Texas and that Respondent failed to timely report the actions.

8. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to timely report).

9. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and is represented in this matter by Ronald J. Friedman, Esq., Karr Tuttle Campbell, 701 Fifth Avenue, Suite 3300, Seattle, Washington 98104.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

//

OCT 15 2015

4. Respondent being at all times relevant herein permitted as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Order issued to Respondent by the Ohio State Board of Pharmacy in Case Number 2013-1421; Exhibit "2" is a true and correct copy of the Consent Order issued to Respondent by the Oregon Board of Pharmacy in Case No. 2015-0142; and Exhibit "3" is a true and correct copy of the Agreed Board Order #L-15-003 issued to Respondent by the Texas State Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2015-134-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's miscellaneous permit to practice in the State of Hawaii is hereby placed on probation for a period of one (1) year. Probation shall become effective immediately upon the approval of this Settlement Agreement by the Board. During the probationary period, Respondent agrees to comply with the following terms and conditions:

2. Administrative fine. Respondent agrees to pay a fine in the amount of TWO THOUSAND FIVE HUNDRED AND NO/100 DOLLARS ($2,500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

3. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 and C.2 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

4. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

5. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.6, C.7, C.8 and C.9 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

6. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

7. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

8. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

//

9. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: April, 5, 2016.

BIOFUSION, LLC
Respondent

By: JOAN SCHUCKENBROCK
Its CAO

DATED: Honolulu, Hawaii, April 6, 2016.

DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

APPROVED AS TO FORM:

RONALD J. FRIEDMAN
Attorney for Respondent

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

2016 JUN -7 A 9:46

HEARINGS OFFICE

RECEIVED

JUN 13 2016

Karr Tuttle Campbell

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	PHA 2015-134-L ERRATA REGARDING SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER FILED ON APRIL 7, 2016 AND APPROVED ON APRIL 28, 2016; CERTIFICATE OF SERVICE

ERRATA REGARDING SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER FILED ON APRIL 7, 2016 AND APPROVED ON APRIL 28, 2016

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE ("Petitioner"), through its undersigned attorney, hereby submits this Errata regarding the Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order, approved on April 28, 2016.

The reference on page 2, paragraph A.7 to "California" should be "Ohio." Respondent, by and through Respondent's counsel of record in the above-referenced matter, has approved the change made by this errata.

DATED: Honolulu, Hawaii, JUN - 7 2016.

JOHN T. HASSLER
Attorneys for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	)	PHA 2015-134-L CERTIFICATE OF SERVICE

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was duly served upon Respondent's counsel, Ronald J. Friedman, Esq., at Karr Tuttle Campbell, 701 Fifth Avenue, Suite 3300, Seattle, Washington 98104, by U.S. Mail, postage prepaid, on the date indicated below.

DATED: Honolulu, Hawaii, JUN - 7 2016.

JOHN T. HASSLER
Attorneys for Department of Commerce
and Consumer Affairs

Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO
BOARD OF PHARMACY

ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2013-1421)

In The Matter Of:

Kroger Specialty Infusion CA
(FKA Biofusion, LLC)
1910 Van Ness Ave.
Torrance, CA 90501
(TDDD No. 02-2315800)

Upon consideration of the documents submitted on September 20, 2017, Kroger Specialty Infusion CA, Terminal Distributor of Dangerous Drugs License Number 02-2315800, the State of Ohio Board of Pharmacy (Board), acknowledges the Change in Ownership from Biofusion, LLC to Kroger Specialty Infusion CA and hereby terminates the period of probation and other terms as set forth in the Board's Order dated February 7, 2014.

Kroger Specialty Infusion CA's License number 02-2315800 is now in good standing.

This matter was presented to the full Board on October 10, 2017 for consideration and final vote for termination of the Board's Order dated February 7, 2014.

Megan E. Marchal, R.Ph.
President, State of Ohio Board of Pharmacy

OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143 *E-MAIL:* exec@bop.state.oh.us *FAX:* 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750 *URL:* http://www.pharmacy.ohio.gov

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1421)

In The Matter Of:

BIOFUSION, LLC
c/o SHERRI CHERMAN, R.Ph.
1910 Van Ness Ave.
Torrance, CA 9501

INTRODUCTION

The Matter of Biofusion, LLC came for hearing on January 7, 2014, before the following members of the Board: Kevin J. Mitchell, R.Ph.; (presiding); Edward T. Cain, Public Member; Melinda J. Ferris, R.Ph.; Margaret A. Huwer, R.Ph.; Megan E. Marchal, R.Ph.; Michael A. Moné, R.Ph.; and Kilee S. Yarosh, R.Ph.

Richard F. Kolezynski, R.Ph., Absent.

Biofusion, LLC was not present and Biofusion, LLC. is represented by Stacie K. Neroni, who also was not present. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. Sheri Zapadka, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Copy of Proposal to Deny/Notice of Opportunity for hearing letter	[10-15-13]
1A-1C.	Procedurals	
2.	Correspondence from Staci K. Neroni; Application for Out of State Terminal Distributor of Dangerous Drugs License	[04-19-13]

Respondent's Exhibits:

A.	Contentions	[11-14-13]

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

(1) Records of the Board of Pharmacy indicate that on or about April 2, 2013, Sherri Cherman was the President of Biofusion, 19110 Van Ness Ave., Torrance, California and that on said date, Biofusion submitted an application for registration as a Terminal Distributor of Dangerous Drugs.

(2) On or around October 10, 2011, Modern Healthcare, Inc. D.B.A AD-Rx Pharmacy entered into a Stipulated Settlement and Disciplinary Order with the California State Board of Pharmacy concerning the loss of approximately 470,000 tablets of hydrocodone/APAP 10/325 mg tablets due to employee pilferage. In the Matter of the Accusation Against: Modern Healthcare, Inc., d.b.a., AD-Rx Pharmacy and Robert Antoine Charles, Case No. 3539. Modern Healthcare, Inc. is listed as an owner of Biofusion, the applicant. Such conduct, if proven, constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

(3) The applicant has failed to furnish satisfactory proof to the Board that adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs as required by Ohio Revised Code Section 4729.55(C). To wit: another pharmacy owned by the same company did, on or before May 17, 2012, experience significant loss of controlled substances. Such loss was attributable to the actions of a pharmacy employees and poor recordkeeping. Such conditions violate, or allow the violation of Section 4729.55 of the Ohio Revised Code, and constitute a failure to meet the qualifications for a Terminal Distributor of Dangerous Drugs.

DECISION OF THE BOARD

Pursuant to Section 4729.11 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the Application for Registration as a terminal Distributor of Dangerous Drugs submitted by Biofusion, L.L.C. on or about April 2, 2013.

Further, State Board of Pharmacy hereby places on probation for a period of five years the Terminal Distributor License, issued to Biofusion, LLC effective as of the date the license becomes active. The terms of probation are as follows:

(A) Biofusion, L.L.C. must submit to this Board annual reports of any theft or loss of drugs during the period of probation.

(B) Biofusion, LLC must not violate the drug laws of Ohio, any other state, or the federal government.

(C) Biofusion, LLC must abide by the rules of the State Board of Pharmacy.

(D) Biofusion, LLC must comply with the terms of this Order.

(E) Biofusion, LLC's license is deemed to be not in good standing until successful completion of the probationary period.
(F) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Biofusion, LLC is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

Margaret Huwer moved for Findings of Fact; Megan Marchal seconded the motion. Motion passed (Aye-6/Nay-0).

Megan Marchal moved for Action of the Board; Michael Moné seconded the motion. Motion passed (Aye-5/Nay-1).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

Section 119.12 of the Ohio Revised Code authorizes an appeal from this Order. An order that denied admission to an examination, or denied the issuance or renewal of a license or registration, or revoked or suspended a license, may be appealed to the court of common pleas in the Ohio county of your place of business or in your Ohio county of residence. Any other order may be appealed to the Court of Common Pleas of Franklin County, Ohio.

Such an appeal, setting forth the order appealed from and the grounds of the appeal, must be commenced by the filing of the ORIGINAL Notice of Appeal with the State Board of Pharmacy and a copy with the appropriate court within fifteen (15) days after the mailing of this Order and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: 2-7-14

By: _____
Kyle W. Parker, M.B.A., R.Ph., Executive Director

KWP/ljp
Certified Mail / Return Receipt
7004 1160 0000 5912 7454
c: Charissa D. Payer, Assistant Attorney General
Stacie K. Neroni, Esq.

Oregon
Kate Brown, Governor

Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971/673-0001
Fax: 971/673-0002
Email: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

April 19, 2017

Kroger Specialty Infusion CA

RE: Case # 2015-0142
Kroger Specialty Infusion CA (formerly known as BioFusion LLC)
Oregon Registration No. RP-0002741

This letter will confirm the end of Kroger Specialty Infusion CA's Oregon probation issued in Case No. 2015-0142. The completion date for Kroger Specialty Infusion CA's Board ordered probation was 9/2/2016 pursuant to documentation received on 4/19/2017 from the California State Board of Pharmacy.

It is the Board's desire that Kroger Specialty Infusion CA, continue its practice in accordance with all pharmacy laws and rules in order to avoid further action by the Board against its license.

Should you have any questions concerning your practice in the future, you are encouraged to call the Board office for assistance.

Sincerely,

Brianne Efremoff, Pharm.D, R.Ph.
Compliance Director

CC: Licensing Department

BE/ag

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2015-0142
BIOFUSION LLC dba: BIOFUSION	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits, as described in the Notice, that action was taken against a separate corporate entity ModernHEALTH Specialty (AD-RX), LLC which is owned by the same parent company (Modern HC Pharmacy, Inc.) as the registrant, for AD-RX's violation of rules and statute in California in Board of Pharmacy #3539, and whereas the registrant does not contest lawful cause pursuant to ORS 689.405 for disciplinary action by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby imposes the following sanctions:

1. The registrant is placed on probation with the Oregon Board of Pharmacy for the duration of probation with the California Board of Pharmacy. Registrant shall comply with their probation with the California Board of Pharmacy and the following conditions of probation:
   a. The registrant must comply with all laws and rules.
   b. The registrant will notify the Board of all proposed, pending, and additional action against registrant within 15 days of registrant being notified of proposed, pending, or additional action against registrant.

2. Failure of the registrant to comply with all the requirements of this Consent Order

constitutes unprofessional conduct and is grounds for revocation or any other form of discipline or sanction authorized by law.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

8/27/15

Authorized Representative
BIOFUSION LLC dba:
Biofusion
Registrant (Registration No. RP-0002741)

Date

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

8/27/15

Gary Miner, R.Ph.,
Compliance Director

Date

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of BIOFUSION LLC dba: BIOFUSION Registrant	)	Case No. 2015-0142 NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. RP-0002741 because Biofusion violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

On or about 2/7/2014, Biofusion was placed on a 5 year probation with the Ohio Board of Pharmacy in Case Number 2013-1421. Findings of Fact include that Modern Healthcare dba: AD-Rx Pharmacy entered into a Stipulated Settlement and Disciplinary Order with the California State Board of Pharmacy concerning the loss of approximately 470,000 hydrocodone/APAP 10/325 mg tablets due to employee pilferage. In the Matter of the Accusation Against: Modern Healthcare, d.b.a., AD-Rx Pharmacy and Robert Antoine Charles, Case No. 3539. Modern Healthcare Inc. is listed as an owner of Biofusion.

On or about 4/2/2012, in Case No. 3539 the California Board of Pharmacy placed Modern Health Care, dba: AD-RX Pharmacy on probation for the loss of 470,000 hydrocodone/APAP 10/325 mg tablets from December 2006 to June 2007. Respondent agreed that at hearing the complainant could establish a factual basis for the charges in the Accusation. Case No. 3539 Accusation causes for discipline included failure to maintain adequate security for dangerous drugs, failure to maintain current inventory and complete accountability, and failure to timely notify the Board of a designated pharmacist in charge.

The above conduct is in violation and grounds for discipline, pursuant to OAR 855-041-1010(1) and (2), OAR 855-041-1020(1) and (2), OAR 855-019-0300(1) and (4)(a), OAR 855-041-1170(1), and 689.405(1)(a), (e)(B), and (j).

Based on these alleged violations, the Board proposes to revoke your registration and impose a $10,000 civil penalty per violation.

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request

for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

(a) An admission or denial of each factual matter alleged in the notice;

(b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause;

(a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;

(b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;

(c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and

(d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Gary Miner, R.Ph.,
Compliance Director

7/20/15
Date

DATE OF MAILING 7/21/2015

2016 APR 28 P 2:26
DEPT. OF COMMERCE AND CONSUMER AFFAIRS
HEARINGS OFFICE

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	PHA 2015-134-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" THROUGH "3"

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent BIOFUSION, LLC (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under permit number PMP 908. The permit was issued on or about January 1, 2014. The permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is 19110 Van Ness Avenue, Torrance, California 90501.

3. RICO received a request for investigation from the Board of Pharmacy after Respondent reported disciplinary actions on a December 2, 2015 renewal application.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

4. Respondent attached a copy of an Order issued to Respondent by the Ohio State Board of Pharmacy in Case Number 2013-1421 (hereinafter "the Ohio Order") (Exhibit "1"). The Ohio Order was based on disciplinary action taken by the State of California against Respondent's corporate owner (also a permitted pharmacist), alleging failure to account for medications due to employee pilferage. Respondent's Ohio permit was placed on probation for five years with conditions.

5. Respondent also attached a copy of a Consent Order issued to Respondent by the Oregon Board of Pharmacy in Case No. 2015-0142 (hereinafter "the Oregon Order") (Exhibit "2"). The Oregon Order was also based on the California action against Respondent's corporate owner and imposed probation with conditions.

6. Respondent also attached a copy of Agreed Board Order #L-15-003 issued to Respondent by the Texas State Board of Pharmacy in Agreed Board Order #L-15-003 (hereinafter "the Texas Order") (Exhibit "3"). The Texas Order was also based on the California action against Respondent's corporate owner and imposed probation, with conditions, including a $1,200.00 probation fee.

7. RICO alleges that disciplinary action was taken against Respondent by the States of California, Oregon, and Texas and that Respondent failed to timely report the actions.

8. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to timely report).

9. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and is represented in this matter by Ronald J. Friedman, Esq., Karr Tuttle Campbell, 701 Fifth Avenue, Suite 3300, Seattle, Washington 98104.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

//

4. Respondent being at all times relevant herein permitted as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Order issued to Respondent by the Ohio State Board of Pharmacy in Case Number 2013-1421; Exhibit "2" is a true and correct copy of the Consent Order issued to Respondent by the Oregon Board of Pharmacy in Case No. 2015-0142; and Exhibit "3" is a true and correct copy of the Agreed Board Order #L-15-003 issued to Respondent by the Texas State Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2015-134-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's miscellaneous permit to practice in the State of Hawaii is hereby placed on probation for a period of one (1) year. Probation shall become effective immediately upon the approval of this Settlement Agreement by the Board. During the probationary period, Respondent agrees to comply with the following terms and conditions:

2. Administrative fine. Respondent agrees to pay a fine in the amount of TWO THOUSAND FIVE HUNDRED AND NO/100 DOLLARS ($2,500.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

3. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 and C.2 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

4. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

5. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.6, C.7, C.8 and C.9 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

6. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

7. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

8. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

//

9. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: April, 5, 2016.

BIOFUSION, LLC
Respondent

By: JOAN SCHUCKENBROCK
Its CAO

DATED: Honolulu, Hawaii, April 6, 2016.

DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

APPROVED AS TO FORM:

RONALD J. FRIEDMAN
Attorney for Respondent

STATE OF Florida)
) SS.
COUNTY OF Orange)

On this 5th day of April, 2016, before me personally appeared Joan Schuckenbruck, to me known to be the person described, and who executed the foregoing instrument on behalf of Biofusion, LLC as its _____, and acknowledged that he/she executed the same as his/her free act and deed.

This 5th -page Settlement Agreement. document dated April 5th, 2016 was acknowledged before me by Joan Schuckenbruck this 5th day of April, 2016, in the City of Orlando, in the County of Orange, in the State of Florida.

Carolyn Rivera # FF 912097
Name:
Notary Public, State of

My Commission expires: Aug 24, 2019

CAROLYN RIVERA
Notary Public - State of Florida
Commission # FF 912097
My Comm. Expires Aug 24, 2019
Bonded through National Notary Assn.

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF BIOFUSION, LLC; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" THROUGH "3"; CASE NO(S). PHA 2015-134-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

Kerri Okamura
KERRI OKAMURA
Chairperson

4/28/16
DATE

GARRETT A. LAU
Vice Chairperson

MARCELLA CHOCK

Mary Jo Keefe
MARY JO KEEFE

CAROLYN S. J. MA

PVL 07/01/15

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

2016 JUN -7 A 9:46

HEARINGS OFFICE

RECEIVED

JUN 13 2016

Karr Tuttle Campbell

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	PHA 2015-134-L ERRATA REGARDING SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER FILED ON APRIL 7, 2016 AND APPROVED ON APRIL 28, 2016; CERTIFICATE OF SERVICE

ERRATA REGARDING SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER FILED ON APRIL 7, 2016 AND APPROVED ON APRIL 28, 2016

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE ("Petitioner"), through its undersigned attorney, hereby submits this Errata regarding the Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order, approved on April 28, 2016.

The reference on page 2, paragraph A.7 to "California" should be "Ohio." Respondent, by and through Respondent's counsel of record in the above-referenced matter, has approved the change made by this errata.

DATED: Honolulu, Hawaii, JUN - 7 2016.

JOHN T. HASSLER
Attorneys for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF BIOFUSION, LLC; PHA 2015-134-L; ERRATA REGARDING SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER FILED ON APRIL 7, 2016 AND APPROVED ON APRIL 28, 2016; CERTIFICATE OF SERVICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of BIOFUSION, LLC, Respondent.	)	PHA 2015-134-L CERTIFICATE OF SERVICE

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was duly served upon Respondent's counsel, Ronald J. Friedman, Esq., at Karr Tuttle Campbell, 701 Fifth Avenue, Suite 3300, Seattle, Washington 98104, by U.S. Mail, postage prepaid, on the date indicated below.

DATED: Honolulu, Hawaii, JUN - 7 2016.

JOHN T. HASSLER
Attorneys for Department of Commerce
and Consumer Affairs

OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143 *E-MAIL:* exec@bop.state.oh.us *FAX:* 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750 *URL:* http://www.pharmacy.ohio.gov

THIS IS A RECORD STAMP

State Board of Pharmacy

By: Executive Director

2-7-14

MUST HAVE BOARD SEAL TO BE OFFICIAL

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1421)

In The Matter Of:

BIOFUSION, LLC
c/o SHERRI CHERMAN, R.Ph.
1910 Van Ness Ave.
Torrance, CA 9501

INTRODUCTION

The Matter of Biofusion, LLC came for hearing on January 7, 2014, before the following members of the Board: Kevin J. Mitchell, R.Ph.; (presiding); Edward T. Cain, Public Member; Melinda J. Ferris, R.Ph.; Margaret A. Huwer, R.Ph.; Megan E. Marchal, R.Ph.; Michael A. Moné, R.Ph.; and Kilee S. Yarosh, R.Ph.

Richard F. Kolezynski, R.Ph., Absent.

Biofusion, LLC was not present and Biofusion, LLC. is represented by Stacie K. Neroni, who also was not present. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness:

1. Sheri Zapadka, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

None

State's Exhibits:

1.	Copy of Proposal to Deny/Notice of Opportunity for hearing letter	[10-15-13]
1A-1C.	Procedurals	
2.	Correspondence from Staci K. Neroni; Application for Out of State Terminal Distributor of Dangerous Drugs License	[04-19-13]

Respondent's Exhibits:

A.	Contentions	[11-14-13]

EXHIBIT "1"

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

(1) Records of the Board of Pharmacy indicate that on or about April 2, 2013, Sherri Cherman was the President of Biofusion, 19110 Van Ness Ave., Torrance, California and that on said date, Biofusion submitted an application for registration as a Terminal Distributor of Dangerous Drugs.

(2) On or around October 10, 2011, Modern Healthcare, Inc. D.B.A AD-Rx Pharmacy entered into a Stipulated Settlement and Disciplinary Order with the California State Board of Pharmacy concerning the loss of approximately 470,000 tablets of hydrocodone/APAP 10/325 mg tablets due to employee pilferage. In the Matter of the Accusation Against: Modern Healthcare, Inc., d.b.a., AD-Rx Pharmacy and Robert Antoine Charles, Case No. 3539. Modern Healthcare, Inc. is listed as an owner of Biofusion, the applicant. Such conduct, if proven, constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

(3) The applicant has failed to furnish satisfactory proof to the Board that adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs as required by Ohio Revised Code Section 4729.55(C). To wit: another pharmacy owned by the same company did, on or before May 17, 2012, experience significant loss of controlled substances. Such loss was attributable to the actions of a pharmacy employees and poor recordkeeping. Such conditions violate, or allow the violation of Section 4729.55 of the Ohio Revised Code, and constitute a failure to meet the qualifications for a Terminal Distributor of Dangerous Drugs.

'15 DEC -

DECISION OF THE BOARD

Pursuant to Section 4729.11 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the Application for Registration as a terminal Distributor of Dangerous Drugs submitted by Biofusion, L.L.C. on or about April 2, 2013.

Further, State Board of Pharmacy hereby places on probation for a period of five years the Terminal Distributor License, issued to Biofusion, LLC effective as of the date the license becomes active. The terms of probation are as follows:

(A) Biofusion, L.L.C. must submit to this Board annual reports of any theft or loss of drugs during the period of probation.

(B) Biofusion, LLC must not violate the drug laws of Ohio, any other state, or the federal government.

(C) Biofusion, LLC must abide by the rules of the State Board of Pharmacy.

(D) Biofusion, LLC must comply with the terms of this Order.

(E) Biofusion, LLC's license is deemed to be not in good standing until successful completion of the probationary period.
(F) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Biofusion, LLC is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

Margaret Huwer moved for Findings of Fact; Megan Marchal seconded the motion. Motion passed (Aye-6/Nay-0).

Megan Marchal moved for Action of the Board; Michael Moné seconded the motion. Motion passed (Aye-5/Nay-1).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

Section 119.12 of the Ohio Revised Code authorizes an appeal from this Order. An order that denied admission to an examination, or denied the issuance or renewal of a license or registration, or revoked or suspended a license, may be appealed to the court of common pleas in the Ohio county of your place of business or in your Ohio county of residence. Any other order may be appealed to the Court of Common Pleas of Franklin County, Ohio.

Such an appeal, setting forth the order appealed from and the grounds of the appeal, must be commenced by the filing of the ORIGINAL Notice of Appeal with the State Board of Pharmacy and a copy with the appropriate court within fifteen (15) days after the mailing of this Order and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: 2-7-14

By: _____
Kyle W. Parker, M.B.A., R.Ph., Executive Director

KWP/ljp
Certified Mail / Return Receipt
7004 1160 0000 5912 7454
c: Charissa D. Payer, Assistant Attorney General
Stacie K. Neroni, Esq.

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2015-0142
BIOFUSION LLC dba: BIOFUSION	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits, as described in the Notice, that action was taken against a separate corporate entity ModernHEALTH Specialty (AD-RX), LLC which is owned by the same parent company (Modern HC Pharmacy, Inc.) as the registrant, for AD-RX's violation of rules and statute in California in Board of Pharmacy #3539, and whereas the registrant does not contest lawful cause pursuant to ORS 689.405 for disciplinary action by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby imposes the following sanctions:

1. The registrant is placed on probation with the Oregon Board of Pharmacy for the duration of probation with the California Board of Pharmacy. Registrant shall comply with their probation with the California Board of Pharmacy and the following conditions of probation:
   a. The registrant must comply with all laws and rules.
   b. The registrant will notify the Board of all proposed, pending, and additional action against registrant within 15 days of registrant being notified of proposed, pending, or additional action against registrant.

2. Failure of the registrant to comply with all the requirements of this Consent Order

EXHIBIT "2"

constitutes unprofessional conduct and is grounds for revocation or any other form of discipline or sanction authorized by law.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

Authorized Representative — Date: 8/27/15
BIOFUSION LLC dba:
Biofusion
Registrant (Registration No. RP-0002741)

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Gary Miner, R.Ph., — Date: 8/27/15
Compliance Director

RECEIVED
15 DEC -4 P6:18

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2015-0142
BIOFUSION LLC dba: BIOFUSION	)	NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED
Registrant	)	

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. RP-0002741 because Biofusion violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

On or about 2/7/2014, Biofusion was placed on a 5 year probation with the Ohio Board of Pharmacy in Case Number 2013-1421. Findings of Fact include that Modern Healthcare dba: AD-Rx Pharmacy entered into a Stipulated Settlement and Disciplinary Order with the California State Board of Pharmacy concerning the loss of approximately 470,000 hydrocodone/APAP 10/325 mg tablets due to employee pilferage. In the Matter of the Accusation Against: Modern Healthcare, d.b.a., AD-Rx Pharmacy and Robert Antoine Charles, Case No. 3539. Modern Healthcare Inc. is listed as an owner of Biofusion.

On or about 4/2/2012, in Case No. 3539 the California Board of Pharmacy placed Modern Health Care, dba: AD-RX Pharmacy on probation for the loss of 470,000 hydrocodone/APAP 10/325 mg tablets from December 2006 to June 2007. Respondent agreed that at hearing the complainant could establish a factual basis for the charges in the Accusation. Case No. 3539 Accusation causes for discipline included failure to maintain adequate security for dangerous drugs, failure to maintain current inventory and complete accountability, and failure to timely notify the Board of a designated pharmacist in charge.

The above conduct is in violation and grounds for discipline, pursuant to OAR 855-041-1010(1) and (2), OAR 855-041-1020(1) and (2), OAR 855-019-0300(1) and (4)(a), OAR 855-041-1170(1), and 689.405(1)(a), (e)(B), and (j).

Based on these alleged violations, the Board proposes to revoke your registration and impose a $10,000 civil penalty per violation.

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DEC -4 P6
PROFESSIONAL

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request

for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

RECEIVED
DEC -4 P6:18

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

(a) An admission or denial of each factual matter alleged in the notice;

(b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause;

(a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;

(b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;

(c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and

(d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Gary Miner

Gary Miner, R.Ph.,
Compliance Director

7/20/15
Date

DATE OF MAILING 7/21/2015

RECEIVED
'15 DEC -4 P6:18

AGREED BOARD ORDER #L-15-003

RE: IN THE MATTER OF
BIOFUSION
(PHARMACY LICENSE #27196)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 27196 issued to Biofusion (Respondent), 19110 Van Ness Avenue, Torrance, California 90501.

By letter dated July 13, 2015, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(9) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013), as alleged in the Count below.

The conduct described in the Order of the Ohio State Board of Pharmacy is substantially similar to conduct described in:

> Section 565.002(a)(9) and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and
>
> Section 291.32(b)(2) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

COUNT

On or about February 7, 2014, the Ohio State Board of Pharmacy entered an Order against the application for registration as a terminal distributor of dangerous drugs of Biofusion, LLC. The Order was based on findings of fact that a listed owner of Biofusion, LLC (i.e., Modern Healthcare, Inc., d.b.a. AD-RX Pharmacy) had been subject to a Settlement and Disciplinary Order entered by the California Board of Pharmacy on October 10, 2011, for employee diversion of approximately 470,000 tablets of hydrocodone/APAP 10/325 mg tablets. Based on this finding, the Ohio State Board of Pharmacy determined Biofusion, LLC failed to furnish proof of adequate safeguards to prevent the sale or other distribution of dangerous drugs in an unauthorized manner. The Order granted the registration subject to a five-year probation.

An informal conference was held in the Board's office on September 2, 2015, with James Markis, Pharm.D., Director of Pharmacy, Biofusion; Michael R. Hess, General Counsel, Biofusion; Joan Schuckenbrock, Chief Administrative Officer, Modern Health, on behalf of Respondent; and Nanette K. Beaird, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board

EXHIBIT "3"

Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Caroline Hotchkiss, Assistant General Counsel. Ginger Shuffer, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Joan Schuckenbrock and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent's license shall be placed on probation for a period of two (2) years, with such period to commence thirty (30) days after the entry of this Order. During the period of probation, Respondent shall abide by the terms of this Order, and shall not violate any pharmacy or drug statute or rule of this state, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs.

(2) Respondent shall pay a probation fee of one thousand two hundred dollars ($1,200) due one hundred twenty (120) days after the entry of this Order.

(3) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015).

'15 DEC -4 P6:18

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 3rd day of November, 2015.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Joan Schuckenbrock, Chief Administrative Officer, Modern Health
For and on behalf of Biofusion

Nanette K. Beaird, Legal Counsel for Biofusion
Gardere, Wynne, Sewell, LLP
600 Congress Avenue, Suite 3000
Austin, Texas 78701

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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15 DEC -4 P 6:18

AGREED BOARD ORDER #L-15-003

RE: IN THE MATTER OF
BIOFUSION
(PHARMACY LICENSE #27196)

BEFORE THE TEXAS STATE
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And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 3rd day of November, 2015.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Joan Schuckenbrock, Chief Administrative Officer, Modern Health
For and on behalf of Biofusion

Nanette K. Beaird, Legal Counsel for Biofusion
Gardere, Wynne, Sewell, LLP
600 Congress Avenue, Suite 3000
Austin, Texas 78701

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Kroger Specialty Infusion CA

NV Pharmacy or Outsourcing facility license # (if applicable): PH02247

Physical Address: 19110 Van Ness Ave.

City: Torrance State: CA Zip: 90501

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 310-320-6444 Toll Free # (NAC 639.708, NRS 639.23286): 866-202-9552

Fax: 866-794-4844 Contact Email: license@bioplusrx.com

Website: https://www.krogerspecialtypharmacy.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Kirankumar Patel

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21368

Name of Person with direct knowledge of compounding procedures: Kirankumar Patel

Email of Person with direct knowledge of compounding procedures: Kirankumar Patel

Telephone of Person with direct knowledge of compounding procedures: 310 755 2199

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ■ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

- We will not be providing Sterile Compounded products for patients or consumers that reside in the state of Nevada.

- We only prepare and dispense Sterile Compounded products to patients or consumers that reside in the state of California.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ■ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Pharmacist reviews Work Order/Compounding record for product to be dispensed. Review of medication and supplies utilized to prepare compounded item. Final product is visually inspected utilizing a black and white background to check for particulate matter/cloudiness. Final product is weighed and documented as to time of final check.

8. How often do you perform glove fingertip and medial fill testing?

Two times per 12 month period (Every 6 months)

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Personnel who fail this test will require re-training and may not compound sterile products until tests have been repeated with successful results. On failed gloved test, the genus of growth colony will be identified to determine source of contamination.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

- All desired compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than three times before initially being allow to compound sterile products, this includes media transfer test.
- Immediately after the compounding employee completes the garbing procedure and prior to any disinfection with sterile alcohol, a gloved fingertip/thumb sample will be collected from both hands onto the agar plate. A surface sample is taken.
- The plates are to be incubated per USP 797 recommendation. If BD BBL Plates with Trypticase Soy Agar with Lecithin & Polysorbate 80 are used, they are to be incubated at: 30-35°C for no less than 48hrs and them at a temperature of 20-25°C for no less than 5 additional days; or as indicated per manufacture.
- Personnel are also required to pass didactic testing (Sterile Compounding Competency exam & Math Skills)

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

- Disinfectant agent: Isopropyl alcohol, 70% soln (IPA) or equivalent agent per USP 797 appendix; Germicidal agent: TB1-3300; - Sporicidal agent: Peridox RTU, Decon Spore 200-Plus
- Daily: Performed using a sterile low-lint wipe & cleaning agent. Hood: ISO Class 5 cleaned at beginning of each shift, before each batch, not longer than 30 minutes following previous surface disinfection when ongoing compounding activities are occurring, after spills & when surface contamination is known or suspected. ISO 5 LAFW cleaned with sterile water, then germicidal agent & then sterile 70% IPA. Compounding & miscellaneous equipment: Clean pump & filling devices used in the hood. Counter tops cleaned w/sterile water, sterile 70% IPA & germicidal agent. Floors cleaned by mopping once daily with sporicidal agent. Scrub sink w/disinfectant. Tacky mat changed daily or when appropriate. Clean pass-through window daily with disinfectant.

SEE ADDITIONAL SHEET FOR CONTINUATION

12. Who performs the sterile compounding process at your facility?

Sterile compounding is performed by Pharmacy Technicians and Pharmacists that have successfully passed all testing protocols.

13. Who is responsible and accountable for the sterile compounding process at your facility?

A designated person is identified as the responsible party and accountable for sterile compounding; for this facility is notated as the Director of Pharmacy.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All compounded products are shipped using a cooler/insulated packaging to maintain appropriate temperature range for product, utilizing a predetermined quantity of frozen gel packs dependent on the size of cooler box. All packages are coordinated to be shipped priority overnight to minimize time in transit to recipient.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)	
1. List the specific high risk sterile products that your facility compounds:	
2. What sterilization methods are utilized at your facility?	
3. Does your facility utilize biological indicators?	☐ Yes ☐ No
4. If yes, describe how they are utilized:	

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirankumar Patel

Name of Person who Completed the Form

Sr. Director of Pharmacy Operations

Title

Signature (copies or stamps not accepted)

7/10/2024

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

Nevada State Board of Pharmacy: Sterile Compounding Questionnaire – Continued

Kroger Specialty Infusion CA – PH02247

Section 2, Question #11:

- Weekly: Cleaning procedures (in additional to daily):
  - Sporicidal agent used to sanitize ISO5/7/8 areas; alternated monthly.
  - Clean all chair, counter tops, carts, door handles, windows, ledges, pass-through, trash bins/barrels.
  - Wash cleaning equipment with isopropyl alcohol, 70% solution.
  - Trash bags will be replaced daily or when appropriate.
  - Clean the light fixtures & ceiling in the compounding room and Ante-area.
  - Walls and ceilings will be cleaned once a week with sporicidal agent (Peridox RTU or Decon Spore 200-Plus, products to be altered each month. A lint-free mop labeled "Walls/Ceilings" will be used.
  - Clean interiors and exteriors of cabinets, storage carts/bins, racks and sink.

- Monthly: Cleaning procedures (in addition to daily and weekly):
  - Documentation with date/time of cleaning will be made on internal form for record keeping.

- Clean LAFH/PEC pre-filters every other month, or when appropriate, based on manufacturer recommendation.

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	KROGER SPECIALTY INFUSION CA, LLC
Entity No.:	201220510197
Registration Date:	09/09/2005
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 08, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 226649533

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 7/15/2024 Inspector: Lyle Matthews

Firm: KROGER SPECIALTY INFUSION CA Phone: (866) 202-9552

Address: 19110 VAN NESS AVE City: TORRANCE Zip: 90501

Ownership: CORPORATION

Permit #: LSC101016 PHY54649 Permit Exp: 9/1/2024 DEA#: FB3417602 DEA Exp: 12/31/2024

Date of Self Assessment Form: 2/9/2023 Other Permit #: N/A Date of DEA Inventory: 12/27/2022

Hours M-F: 0900 - 1730 Hours Saturday CLOSED Hours Sunday: CLOSED

PIC ___ Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:
KIRANKUMAR K PATEL	RPH69538
LUCIA M RIVA	RPH47522
MATTHEW P CAPLIS	RPH75215
ROZALIYA VEYTSMAN-SHPI	RPH73419
JEFFREY JOHNSON	RPH56840
DAVID T NGUYEN	RPH72370
GILBERTO G MELO	RPH52387

Staff Name:	License #:
ALLISON VENIDALUC	TCH133903
CRYSTAL GONZALEZ	TCH75496
GINA M LIMON	TCH95877
HECTOR JIMENEZ	TCH68261
JACKYLINE C GARCIA	TCH83610
JUSTIN C LIVELO	TCH150668
LIZETH SERRANO	TCH149641
LUCCI R SAN JOSE	TCH101163
NEARADA NGOV	TCH144733
RAFAEL TORO	TCH75930
RENEE A RAMOS	TCH161849
RICHARD F NOA	TCH86303
TAVIA M GRAVETT-FLESHM	TCH89488

Inspector Remarks:

Performing on-site annual sterile compounding renewal inspection at Kroger Specialty Infusion Pharmacy in Torrance, CA. PIC Gilberto (Gilbert) Melo is present and assisting in the inspection. PIC Melo has been with Kroger Specialty Infusion Pharmacy since 2018.

PIC Melo's Contact information is: e-mail: gilberto.melo@krogerhealth.com Phone: 866-202-9552

Kroger Specialty Infusion Pharmacy is a closed door specialty infusion pharmacy which primarily (98%) compounds Intravenous Immune Globulin (IVIG). They also have a few patients who receive other infusion therapies (Entyvio, Tysabri, Rituxan, Ceprotin), but

INSPECTION REPORT

those are very few. They currently have approximately 400 California residents and approximately 200 non-CA residents on service for primarily IVIG therapy.

The facility is located in a large business complex in Torrance, CA. There is parking outside for staff. Upon entry to the facility there is a reception area. This opens up to a large work area with several cubicle work spaces for billing staff, etc. There is another open area for pharmacist and technicians to process orders, etc. There is a large conference room, staff breakroom, restrooms, etc. Non-resident pharmacy licenses are posted in breakroom hallway

This facility is part of the Kroger Specialty Pharmacy network which includes other Specialty Infusion locations in Texas and Alabama. Non-Infusion Kroger Specialty Pharmacies are located in Garden Grove, CA, along with others across the country including in Louisiana and Florida.

Some patients come to the Torrance facility to receive their infusion at the on-site 3-bed infusion center. There is a third-party contracted nursing agency who administers the on-site infusions when necessary. The infusion center is not used every day.

Kroger Specialty pharmacy dispenses IVIG to patient in their home and occasionally to the physician office. They are licensed in approximately 40 states across the U.S..

Kroger currently has approximately 12 patients in CA who receive compounded IVIG. These doses are compounded in the on-site sterile compounding suite and shipped to the patient's home. Compounding does not take place every day. IVIG is compounded approximately 3 days per week. Only 1 or 2 doses of IVIG are compounded on any given day in the sterile compounding suite. A 10-day BUD is assigned to compounded IVIG doses.

Concomitant therapies are dispenses including Acetaminophen, Diphenhydramine, Solu-Medrol, etc. related to IVIG therapy. Epi-Pens are dispensed in case of allergic reactions. There are no hazardous or cytotoxic drugs in inventory currently. This facility does have a DEA registration, but controlled substances are currently in inventory.

The facility is accredited buy ACHC and URAC. ACHC performed an on-site inspection on April 2024. NABP performed an on-site inspection in April 2023. There were not findings on that inspection.

Fingertip and media fill testing is performed and testing is reviewed internally. There are two incubators in the facility set at 25 and 35 degrees for incubation.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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LSC Inspection:

The compounding area is a two-room suite. There is an ISO8 gowning (ante) room that leads to an ISO7 positive pressure buffer zone with an ISO5 Germfree LFH.

Compounding Area:

- Flooring: Sheet vinyl
- Walls: Clean and washable
- Sink: Stainless steel in Gowning Room
- Emergency Eye Wash Station: In Gowning Room
- Air Pressure Monitoring: Continuous and electronic in Lab Alert system - E-fusion live website
  - Pharmacy staff is notified if out of range
  - Clean room temperature and humidity is recorded as well

Certification:

- Clean Room Services (CRS)
  - Last on 4/29/24
    - Environmental Viable Sampling: Passed during certification
    - Air Exchanges: Passed during certification
    - HEPA Filtration: Passed during certification

Smoke Tests:

- Viewed during inspection with PIC
- Passed during on-site certification on 4/29/24

Gowning Room:

- ISO8
- Air Exchanges Per Hour: 32
- Air Pressures: +0.046
- Line of Demarcation
- Sheet vinyl flooring
- Stainless steel sink
- Stainless steel bench
- Stainless steel table
- Stainless steel cart
- Mirror
- Emergency Eye Wash Station

INSPECTION REPORT

Positive Pressure Buffer Zone:
- ISO7
- Air Exchanges Per Hour: 103
- Air Pressures: +0.0846
- Laminar Flow Hood/Cabinet:
  - ISO5 Germfree LFH
- Stainless steel table
- Low air return
- Pass thru window to unlicensed area
- Large glass wall allowing for direct visual contact from outside sterile compounding area
- Repeater pump in LFH

Non-Hazardous Drugs Prepared:
- N/A

Negative Pressure Buffer Zone:
- N/A

Biological Safety Cabinet:
- N/A

Hazardous Drugs Prepared:
- N/A

CSTD System:
- N/A

PPE/Garbing:
- All required PPE is available in Gowning Room

BUD's:
- 10-days assigned to compounded IVIG doses
  - Category 2 CSPs refrigerated

Labeling:
- Labels reviewed for several medications
  - Gamunex
  - Acetaminophen

INSPECTION REPORT

- Diphenhydramine
- Lidocaine/Prilocaine Cream
- All required elements are present

Shipping:
- Products shipped both within and outside CA are shipped via Federal Express
- All products are shipped in insulated Styrofoam containers
- Policy in place for how to ship depending on temperature of receiving location
- Shipping studies performed with temperature tracking to ensure proper packaging

Adverse Drug Reactions:
- None to report

Master Formula:
- Master formula for compounded IVIG reviewed
- IVIG is simply transferred to empty bags or syringes
- No other ingredients are added to the IVIG transfer

Compounding Log:
- Reviewed for Gammagard liquid 45 gm dose
- All required elements are present
- Compounded on 7/10/24
- Pharmacist reviews drug and supplies prior to compounding
- Pharmacist weighs final bag(s) prior to dispensing

Inventory:
- Pre-Mixed Drips: N/A
- Outsourcing 503B: N/A
- TPN:N/A
- 503A: N/A
- Connector System: N/A

Controlled Substances:
- No controlled substances in inventory
- Quarterly reconciliation documented even though none in inventory
- Documentation is recorded and sent into Kroger compliance group in Florida

Cleaning Documentation:
- Recorded on manual log

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Refrigerator/Freezer Logs:
- Multiple medication refrigerators on site
- Freezers used for ice packs only
- Continuously recorded in Winland system for all refrigerators and freezers

Security:
- One main entry/exit door in front
- Second entry/exit door in back
- Roll up door in back for deliveries
- Security cameras throughout the facility

Cleaning Agents:
- TB1-3300
- Peridox RTU
- Decon-Spore 200 Plus
- Sterile IPA

Training:
- Fingertip testing semi-annually
- Media fill testing semi-annually
- Three technicians and all pharmacist are trained for sterile compounding
- Written exam taken annually
- Written math skills exam annually
- Reviewed documentation for:
  - Technicians R.N. and H.J.

Policy and Procedures:
- SOP manual reviewed
- Reviewed annually by PIC

Quality Assurance Program:
- Process Validation:
  - Magnesium Sulfate 250mg/50ml NS
    - 10/24/23
    - Eagle Labs
      - Potency: 98.0%
      - Sterility: Negative at 14 days
  - Magnesium Sulfate 250mg/50ml NS

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- 4/26/24
- Eagle Labs
  - Potency: 103.6%
  - Sterility: Negative at 14 days

Wholesaler:
- Cardinal

Reverse Distributor:
- Inmar
- Pharmalink (for Sandoz generic products only)

Education During Inspection:
- Security - Always ask for credentials from anyone representing themselves as being from a regulatory agency to ensure they are who they say they are.
- Security - Beware of scam callers representing themselves as being from a regulatory agency who threaten the status of your license and request money. No one from the CA Board of Pharmacy will call and request money.
- Quarterly inventory reconciliation - Be sure to include purchasing records as part of the reconciliation to reconcile the purchases with what is entered into the controlled substance inventory.
- Date and label any open bottle, i.e. sterile IPA to indicate either date of opening and/or expiration date after opening and removal from sterile packaging.

Topics to Educate

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
   - Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.

INSPECTION REPORT

- Retain records for 3 years.

2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.
3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.,* any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.,* before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

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When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.

5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.
7. The Board has posted on its website the FAQ's to address the changes in pharmacy law related AB1286, dated 12/21/2023. Here's the link:
https://pharmacy.ca.gov/publications/ab1286_faqs.pdf

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

If there have been changes in your policies and procedures in the last year, please provide an electronic copy of the new or changed policies and procedures. You may do this by sending a disk or CD to the Board or e-mail the new policies and procedures to: compounding.pharmacy@dca.ca.gov. Please use the pharmacy's California sterile compounding license number (LSC or NSC and five-digit number) on the disk, CD, or in the subject line of the e-mail to ensure proper identification. Please identify or list the changes to your procedures. Failure to identify or list the changes will hinder timely renewal..

Discussion:

Please provide the following to Inspector Matthews at lyle.matthews@dca.ca.gov no later than 8/15/24:
1. N/A

Follow-up questions may be referred to Inspector Matthews at lyle.matthews@dca.ca.gov or to (909) 255-2973.

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INSPECTION REPORT

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____ RPL

Pharmacist (print) Gilberto Melo, RPh.

Inspector (sign) Lyle Matthews, PhD

Inspector (print) Lyle Matthews, Pharm.D

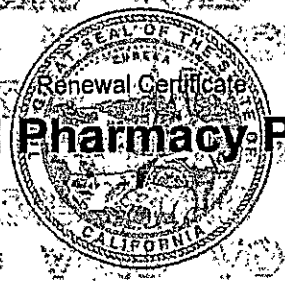
Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:





CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 54649 Valid Until: 9/1/2025

Receipt No. 42012003

KROGER SPECIALTY INFUSION CA
19110 VAN NESS AVE
TORRANCE, CA 90501-1101

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

- - NON-TRANSFERABLE - - POST IN PUBLIC VIEW - -

FORM WPHPHY (09/30/19) PHY

1521

BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

License No. LSC 101016

Valid Until: 9/1/2025

Receipt No. 00193702

KROGER SPECIALTY INFUSION CA
19110 VAN NESS AVE
TORRANCE, CA 90501-1101

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

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--- NON-TRANSFERABLE --- POST IN PUBLIC VIEW ---

WPHLSC 09/30/19

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 54649

NAME: KROGER SPECIALTY INFUSION CA

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

19110 VAN NESS AVE
TORRANCE CA 90501-1101
LOS ANGELES COUNTY

ISSUANCE DATE

SEPTEMBER 2, 2016

EXPIRATION DATE

SEPTEMBER 1, 2025

CURRENT DATE / TIME

AUGUST 28, 2024
7:58:15 AM

LICENSE RELATIONSHIPS

NAME: KROGER SPECIALTY INFUSION CA

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101016 **PRIMARY STATUS:** CLEAR

ADDRESS :
19110 VAN NESS AVE
TORRANCE CA 90501-1101
LOS ANGELES COUNTY

NAME: MELO, GILBERTO GONZALEZ

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 52387 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101016

NAME: KROGER SPECIALTY INFUSION CA

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

19110 VAN NESS AVE
TORRANCE CA 90501-1101
LOS ANGELES COUNTY

ISSUANCE DATE

SEPTEMBER 2, 2016

EXPIRATION DATE

SEPTEMBER 1, 2025

CURRENT DATE / TIME

AUGUST 28, 2024
7:57:55 AM

LICENSE RELATIONSHIPS

NAME: KROGER SPECIALTY INFUSION CA

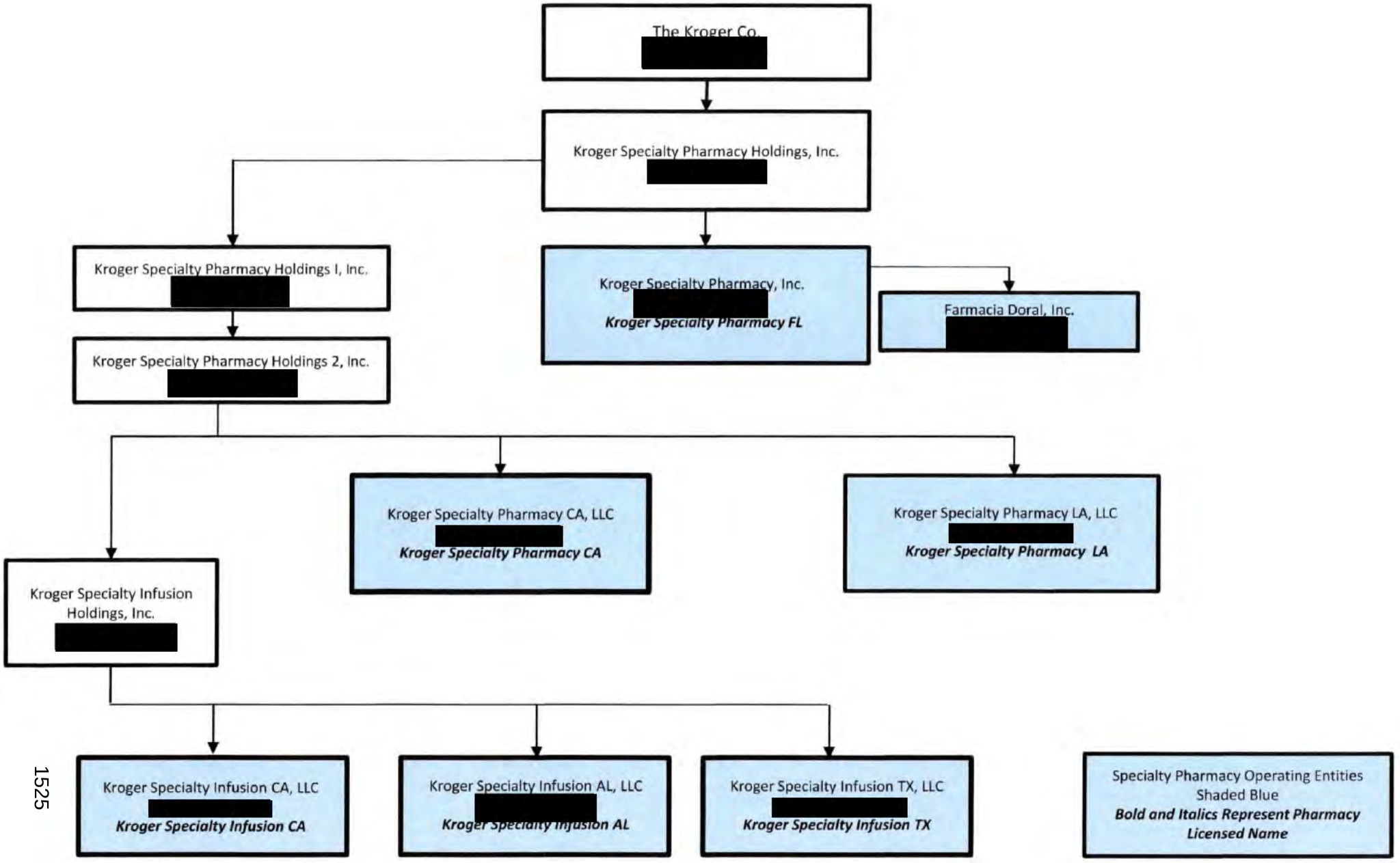
LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 54649 **PRIMARY STATUS:** CLEAR

ADDRESS :
19110 VAN NESS AVE
TORRANCE CA 90501-1101
LOS ANGELES COUNTY

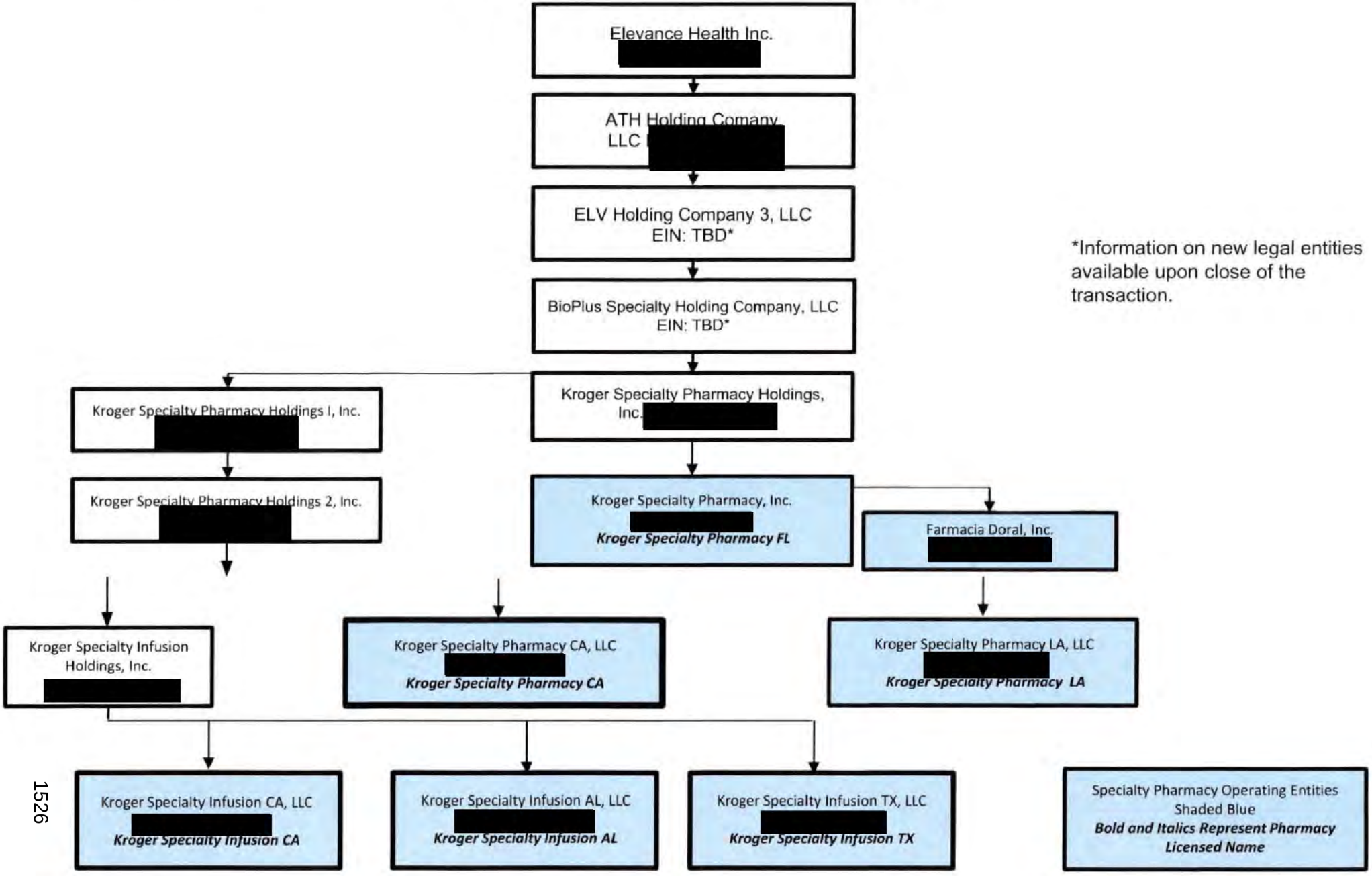
CONFIDENTIAL/EXEMPT FROM FREEDOM OF
INFORMATION ACT AND SIMILAR STATE REQUESTS

Kroger Specialty Pharmacy
Pre-Close Organizational Chart



CONFIDENTIAL/EXEMPT FROM FREEDOM OF
INFORMATION ACT AND SIMILAR STATE REQUESTS

Kroger Specialty Pharmacy
Post Close Organizational Chart



*Information on new legal entities available upon close of the transaction.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Kroger Specialty Infusion CA

Pharmacy/Wholesaler License # (if applicable): PH02247

Physical Address: 19110 Van Ness Ave.

City: Torrance State: CA Zip: 90501

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 310-320-6444 Website: https://www.krogerspecialtypharmacy.com/

Licensing Company Email: license@bioplusrx.com

Section 2: Personal Information

First: Kirankumar Middle: Kanaiyalal Last: Patel

Alias(es, nicknames, name changes, etc.): Kiran Patel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Torrance State: CA Zip: 90503

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California - Alfred E. Mann School of Pharmacy and Pharmaceutical Sci		8/09 - 5/13	
Address	**City**	**State**	**Zip**
1985 Zonal Ave	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Doctorate in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of California, Riverside		08/04 - 06/08	
Address	**City**	**State**	**Zip**
900 University Ave	Riverside	CA	92521
Diploma/Degree obtained, if any			
Bachelor of Science - Biology			

School Name		From - To (MM/YY – MM/YY)	
Yucaipa High School		08/00 - 06/04	
Address	**City**	**State**	**Zip**
33000 Yucaipa Blvd	Yucaipa	CA	92399
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/23 - Current	[redacted]	Torrance	CA	90503
11/20 - 12/23	[redacted]	Los Angeles	CA	90034
5/17 - 11/20	[redacted]	Los Angeles	CA	90066
05/13 - 5/17	[redacted]	Monterey Park	CA	91754
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Kroger Specialty Infusion - CA			06/20 - 7/24	
Business Address		**City**	**State**	**Zip**
19110 Van Ness Ave		Torrance	CA	90501
Phone	**Title**		**Number of Employed Hours**	
866 202 9552	Sr. Director of Pharmacy - Operation		6240	
Description of Duties				
Work with Pharmacy Director to manage pharmacy operations. This includes updating policies, being part of BOP and accreditation inspections, and oversight of receiving and dispensing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Kirankumar Patel, **certify that as the designated representative for**

Kroger Specialty Infusion - CA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KP I am at least 21 years of age;
3. KP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kirankumar Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/10/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirankumar Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/10/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Kirankumar Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/10/2024

Date

Subscribed and Sworn to before me this 10th day of July 2024.

Notary Public Signature

SHARON D. BENNETT
Notary Public - California
Los Angeles County
Commission # 2425970
My Comm. Expires Nov 9, 2026

(Seal)

KROGER SPECIALTY INFUSION CA
19110 VAN NESS AVE.
TORRANCE, CA 90501-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB3417602	12-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	11-09-2021

KROGER SPECIALTY INFUSION CA
19110 VAN NESS AVE.
TORRANCE, CA 90501-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB3417602	12-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	11-09-2021

KROGER SPECIALTY INFUSION CA
19110 VAN NESS AVE.
TORRANCE, CA 90501-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: BP9443956 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Northwest Compounders

Physical Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 503-352-3811 Toll Free # (NAC 639.708, NRS 639.23286): 1 (866) 632-0236

Fax: 503-624-0591 Contact Email: luke@northwestcompounders.com

Website: www.northwestcompounders.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Luke Eilers

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~N/A~~ 24313

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Luke Eilers	NV Pharmacist Registration #: N/A
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Oregon

Parent Company (if any): _____

Corporation/Organization Name: Payless Compounders LLC, DBA Northwest Compounders

Mailing Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Telephone: 503-352-3811 Email: luke@northwestcompounders.com

Contact Person Name: Luke Eilers

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Northwest Compounders (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Luke Eilers

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

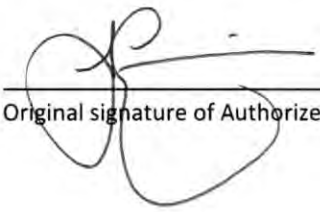
1.27.24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luke Eilers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

Date 11/29/24

Board Use Only	Date Received: 12/5/24	Amount: $500 check 3707

Explanation for "Yes" answer to section 3 of Nevada Pharmacy Application

- On 3/3/2014 we received notice from the Oregon Board of Pharmacy that a fine was being issued to us for one of our technicians actively working with a license that had lapsed and was expired. This occurred due to a lack of oversight into each employee's license status. We have fixed the problem and have not had another occurrence of this since we were fined.



1/29/24

Lukee Eilers

RECEIVED

MAR 03 2014

OREGON BOARD OF PHARMACY

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2013-0465
PAYLESS COMPOUNDERS, LLC dba: NORTHWEST COMPOUNDERS	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits that the facts alleged in the above-noted Notice are true, that legal cause exists pursuant to ORS 689.405 and ORS 689.445 for disciplinary action and imposition of a civil penalty by the Board; and

WHEREAS, the registrant consents to the civil penalty as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The registrant shall pay the Board a civil penalty in the amount of $500 ($1,000 with $500 stayed pending no further similar violation for three years). The $500 payment shall be made within ten days from the date this Consent Order becomes final.

2. Failure of the registrant to pay the civil penalty as required under this Consent Order may, after notice and hearing, result in further disciplinary action.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I further certify that I have read and understand the Notice and this Consent Order and am aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Boards final order. On behalf of the registrant I agree to the Board entering the

Consent Order.

_____	2-26-14
Authorized Representative	Date
PAYLESS COMPOUNDERS, LLC dba	
Northwest Compounders	
Registrant (Reg. No. RP-0002270)	

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

_____	3/4/14
Gary Miner, R.PH.,	Date
Compliance Director	

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug OutletRegistration of PAYLESS COMPOUNDERS, LLC dba: NORTHWEST COMPOUNDERS Registrant	Case No. 2013-0465 NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. RP-0002270 because Northwest Compounders violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

From on or about 9/25/2013 through 10/31/2013, Northwest Compounders, located at 17972 SW McEwan Rd in Tualatin, OR failed to enforce their written procedures for ensuring all who work in the pharmacy are appropriately licensed and registrant employed, allowed, aided, and abetted an unlicensed individual to perform the duties of a pharmacy technician without a pharmacy technician license.

The above conduct is contrary to accepted standards of practice and unprofessional conduct as defined by OAR 855-006-0005(28)(f) and (j) and in violation of OAR 855-025-0035(2),(3), OAR 855-041-1040(7), ORS 689.486(5) which is grounds for discipline pursuant to ORS 689.405(1)(a), (e)(B), (h) and (i).

Based on these alleged violations, the Board proposes to impose a civil penalty in the amount of $5,000 per violation.

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given

information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

- (a) An admission or denial of each factual matter alleged in the notice;
- (b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause;

- (a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;
- (b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;
- (c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and
- (d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Gary Miner, R.Ph.,
Compliance Director

2/18/14
Date

DATE OF MAILING 2/19/2014

Officers and Directors at Northwest Compounders					
First	Middle	**Last**	License #	Expiration	Title
Luke	Thomas	**Eilers**	RPH-0014321	6/30/2025	CEO, Owner, PIC
Thomas	George	**Eilers**	RPH-0006256	6/30/2025	Chariman, Owner
Megan		**Gustafson**	RPH-0018495	6/30/2025	Director of Training
Samuel		**Llona**	RPH-0017452	6/30/2025	Director of Sterile Operations
Vivian	Lan Anh	**Pham**	RPH-0015550	6/30/2025	Senior Operations Manager
Jessie	T	**Vo**	RPH-0012902	6/30/2025	Director of Quality Control, Pharmacy Manager

Owners at Northwest Compounders					
First	Middle	**Last**	License #	Expiration	Ownership Percentage
Luke	Thomas	**Eilers**	RPH-0014321	6/30/2025	42.5%
Thomas	George	**Eilers**	RPH-0006256	6/30/2025	42.5%
Nancy	June	**Eilers**	N/A	N/A	15%

***There are no additional stock holders other than those who are listed above**

Licensee Details

Demographic Information

Name: NORTHWEST COMPOUNDERS

Address Information

Line 1: 8505 SW CREEKSIDE PLACE SUITE 110
Line 2:
Line 3:
Line 4: Beaverton OR 97008

License Information

Type: Retail Drug Outlet
Secondary:
Lic #: RP-0002270
Status: Active
Issued: 7/27/2005
Expiration Date: 3/31/2025
Last Renewed: 3/4/2024

Small Business?	N	N	N

Prerequisite Information

Relationship/Name		Dates		License Details
Self Automatic	NORTHWEST COMPOUNDERS	**Since:**		Controlled Substance RP-000227 **Status:** Active
Pharmacist in Charge	EILERS, LUKE THOMAS	**Since:**	3/25/2020	Pharmacist RPH-0014321 **Status:** Active

Specialty Information

Specialty: Compounding Pharmacy
Issue Date: 3/22/2010
Expiration Date:

Specialty: Community Pharmacy Independent
Issue Date: 3/22/2010
Expiration Date:

Discipline Information

All Board Orders from 2007 to present are displayed below. Board Orders older than 2007 are being added as available. There may be additional disciplinary documents associated with this license/registration. Please submit a public records request.

For additional information regarding public records, click here.

Board Orders

Document Type: Board Order 2013-0465

Licensee Details

Demographic Information

Name: NORTHWEST COMPOUNDERS

Address Information

Line 1: 8505 SW CREEKSIDE PLACE SUITE 110
Line 2:
Line 3:
Line 4: Beaverton OR 97008

License Information

Type: Controlled Substance
Lic #: RP-0002270-CS
Status: Active
Issued: 7/27/2005
Expiration Date: 3/31/2025
Last Renewed: 3/4/2024
Small Business?

Prerequisite Information

Relationship/Name		Dates	License Details
Self Automatic	NORTHWEST COMPOUNDERS	**Since:**	Retail Drug Outlet RP-0002270 **Status:** Active

Discipline Information

No Discipline Information

Board Orders

No Available Board Orders

State of Oregon

OFFICE OF THE SECRETARY OF STATE
Corporation Division

Certificate of Existence 2560175

I, LAVONNE GRIFFIN-VALADE, SECRETARY OF STATE and Custodian of the Seal of said State, do hereby certify:

PAY LESS COMPOUNDERS, LLC

is

Organized

under the laws of The State of Oregon

and is active on the records of the Corporation Division as of the date of this certificate.

In Testimony Whereof, I have hereunto set my hand and affixed hereto the Seal of the State of Oregon.

LAVONNE GRIFFIN-VALADE, SECRETARY OF STATE

Issued Date: 1/29/2024

Come visit us on the internet at: https://sos.oregon.gov/business or use the QR code to check their current status.

Licensee Details

Demographic Information

Name: NORTHWEST COMPOUNDERS

Address Information

Line 1: 8505 SW CREEKSIDE PLACE SUITE 110
Line 2:
Line 3:
Line 4: Beaverton OR 97008

License Information

Type: Retail Drug Outlet
Secondary:
Lic #: RP-0002270
Status: Active
Issued: 7/27/2005
Expiration Date: 3/31/2025
Last Renewed: 3/4/2024

Small Business?	N	N	N

Prerequisite Information

Relationship/Name		Dates		License Details
Self Automatic	NORTHWEST COMPOUNDERS	**Since:**		Controlled Substance RP-000227 **Status:** Active
Pharmacist in Charge	EILERS, LUKE THOMAS	**Since:**	3/25/2020	Pharmacist RPH-0014321 **Status:** Active

Specialty Information

Specialty: Compounding Pharmacy
Issue Date: 3/22/2010
Expiration Date:

Specialty: Community Pharmacy Independent
Issue Date: 3/22/2010
Expiration Date:

Discipline Information

All Board Orders from 2007 to present are displayed below. Board Orders older than 2007 are being added as available. There may be additional disciplinary documents associated with this license/registration. Please submit a public records request.

For additional information regarding public records, click here.

Board Orders

Document Type: Board Order 2013-0465

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Northwest Compounders

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 503-352-3811 Toll Free # (NAC 639.708, NRS 639.23286): 1 (866) 632-0236

Fax: 503-624-0591 Contact Email: Luke@northwestcompounders.com

Website: www.northwestcompounders.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Luke Eilers

Supervising/Managing Pharmacist NV Pharmacist Registration #: N/A

Name of Person with direct knowledge of compounding procedures: Luke Eilers

Email of Person with direct knowledge of compounding procedures: luke@northwestcompounders.com

Telephone of Person with direct knowledge of compounding procedures: 503-352-3811

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Apomorphine SDV Inj (veterinary only)
Cidofovir Ophthalmic Drops (veterinary only)
Cyclosporine Ophthalmic Drops (veterinary only)
Desmopressin Ophthalmic Drops (veterinary only)
Idoxuridine Ophthalmic Drops (veterinary only)
Tacrolimus Ophthalmic Drops (veterinary only)

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Final visual inpsection of compounded sterile products is performed only by pharmacists that have been specifically trained in sterile compounding and are also up to date with media fill, finger tip testing requirements, etc. These pharmacists use a light box located at the final check station that allows them to use regular light and black light to check for impurities, sedimentation, preciptiation and other undesired conditions.

8. How often do you perform glove fingertip and medial fill testing?
FInger tip and media fill testing completed 4 times per year. Two of each under USP <800> conditions.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
If the employee does not correctly demonstrate a core competency criterion, the qualified evaluator must provide remedial training at the conclusion of the assessment. Any activities failed must be re-performed and re-assessed until a passing checkmark is achieved.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial training involves a sterile compounding training manual which is reviewed by the new technician and director of sterile compounding. Sections are reviewed verbally with practical demos reviewing equipment and techniques. Each section is signed when complete. Shadowing is then completed over a multiple month period to give practical application of the material. Then compounding may be started under direct supervision. All techniques are reviewed and practiced. initial fingertip, garbing, dynamic surface sampling and a media fill is completed before a person may perform sterile compounding unassisted.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
CPEC and CSEC daily cleaning and disinfecting on days compounding occurs with sterile 70% IPA includes: CPEC surface and equioment inside CPEC, removal work tray, pass-through chambers, sink, powder containment hood, work surfaces outside the PEC, and floors (with Spartan hdqC2 2 in 1 neutral pH). Weekly sporicidal disinfectant using PeridoxRTU followed by sterile 70% IPA is completed to all locations above. Monthly cleaning with sporicidal disinfectant using PeridoxRTU followed by sterile 70% IPA includes locations already listed plus: Walls, doors, and door frames, ceilings, storage shelving and bins, equipment outside the CPECs.

12. Who performs the sterile compounding process at your facility?
Technicians who have completed sterile compounding training.

13. Who is responsible and accountable for the sterile compounding process at your facility?
Three pharmacists including CEO, Manager, and director of sterile compounding. Technicians who have completed sterile compounding training.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Products are shipped with bubble wrap in secure packaging. If needed products are shipped on ice to control temperature requirements. Hazardous drugs are shipped within plastic bags.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class II Type A2 BSC		
2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API? ✓	☑ Yes	☑ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? All hazardous drug products state "The FDA considers this a hazardous drug. Gloves should be worn when handling." Hazardous drugs are consulted to wear gloves and wash hands.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Initial training involves a sterile compounding training manual which is reviewed by the new technician and director or sterile compounding. Sections are reviewed verbally with practical demos reviewing equipment and techniques. Each section is signed when complete. Shadowing is then completed over a multiple month period to give practical application of the material. Then compounding may be started under direct supervision. All techniques are reviewed and practiced. initial fingertip, garbing, dynamic surface sampling and a media fill is completed before a person may perform sterile compounding unassisted. Hazardous training also includes review of NIOSH hazardous list, review and knowledge of hazardous drug exposure, review of hazardous drug responses to spills, modified containment strategies, and respirator fit testing. Practical testing like media fills are repeated multiple times per year in congruence with USP chapters. Hazardous review is completed annually.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
Assuming high risk sterile products are in reference older USP chapters.

Apomorphine SDV Inj (veterinary only)
Cyclosporine Ophthalmic Drops (veterinary only)
Tacrolimus Ophthalmic Drops (veterinary only)

2. What sterilization methods are utilized at your facility?
Filter sterilization, autoclave sterilization, dry heat sterilization.

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:
Sporview biological indicators are run in our autoclave monthly to confirm cycle validation. Dry heat sterilization is verified annually with biological indicators.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luke Eilers
Name of Person who Completed the Form

CEO
Title

Signature (copies or stamps not accepted)

2/5/24
Date

Board Use Only	Date Received: 2/15/24 Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Northwest Compounders

Pharmacy/Wholesaler License # (if applicable): RP-0002270-CS (OR) Non-resident Nevada License is pending

Physical Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 503-352-3811 Website: www.northwestcompounders.com

Licensing Company Email: luke.nwc@gmail.com

Section 2: Personal Information

First: Luke Middle: Thomas Last: Eilers

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addres[redacted]

City: Tigard State: OR Zip: 97223

Telephone[redacted] Emai[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pacific University School of Pharmacy		09-2011-09-2014	
Address	**City**	**State**	**Zip**
222 SE 8th Ave	Hillsboro	OR	97123
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Oregon State University		09-2006-09-2011	
Address	**City**	**State**	**Zip**
104 Kerr Admin Bldg #1011	Corvallis	OR	97331
Diploma/Degree obtained, if any			
B.S. General Science			

School Name		From - To (MM/YY – MM/YY)	
Ida B. Wells High School		09-2002-09-2006	
Address	**City**	**State**	**Zip**
1151 SW Vermont St	Portland	OR	97219
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10-21-01-24	[redacted]	Tigard	OR	97223
8-17-10-21	[redacted]	Portland	OR	97219
01-14-08-17	[redacted]	Portland	OR	97202
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Northwest Compounders			09-14-current	
Business Address		**City**	**State**	**Zip**
8505 SW Creekside Place Suite 110		Beaverton	OR	97008
Phone	**Title**		**Number of Employed Hours**	
503-352-3811	Pharmacy Manager, COO, CEO		>18,000	
Description of Duties				
Have held postions as the pharmacy manger, COO and now CEO. Have overseen every aspect of the business including all daily operations which incldues the dispensing, distribution and record keeping of all prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Luke Eilers, **certify that as the designated representative for** Northwest Compounders,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Luke Eilers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/29/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luke Eilers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/29/24

Date

Please have this section completed in the presence of a Notary Public.

State of Oregon, ss. County of Washington

I, Luke Eilers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/8/24

Date

Subscribed and Sworn to before me this 8th day of February.

Rachel Manes

Notary Public Signature

OFFICIAL STAMP
RACHEL MANES
NOTARY PUBLIC - OREGON
COMMISSION NO. 1018616A
MY COMMISSION EXPIRES OCTOBER 28, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Northwest Compounders

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): RP-0002270-CS

Physical Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 503-352-3811 Website: www.northwestcompounders.com

Licensing Company Email: luke.nwc@gmail.com

Section 2: Personal Information

First: Thomas Middle: George Last: Eilers

Alias(es, nicknames, name changes, etc.): Tom

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Portland State: OR Zip: 97224

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Central Catholic High School		09/67 – 06/70	
Address	**City**	**State**	**Zip**
2401 SE Stark St.	Portland	OR	97214
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Oregon State University		09/70 - 06/76	
Address	**City**	**State**	**Zip**
1500 SW Jefferson Way	Corvallis	OR	97331
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/16-current	[redacted]	Portland	OR	97224
11/85-01/16	[redacted]	Lake Oswego	OR	97035
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Pay Less Compounders, LLC dba Northwest Compounders			10/05 – current
Business Address	**City**	**State**	**Zip**
8505 SW Creekside Place	Beaverton	OR	97008
Phone	**Title**		
503-352-3811	Founder, owner, member (LLC)		
Description of Duties			
Senior advisor			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas (Tom) Eilers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Oregon, ss. County of Washington

I, Tom (Thomas) Eilers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/9/2024

Date

Subscribed and Sworn to before me this 9th day of February.

Notary Public Signature

OFFICIAL STAMP
RANITHY KABO BEN
NOTARY PUBLIC - OREGON
COMMISSION NO. 1034697
MY COMMISSION EXPIRES MARCH 05, 2027

(Seal)

Scanned with CamScanner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Northwest Compounders

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): RP-0002270-CS

Physical Address: 8505 SW Creekside Place Suite 110

City: Beaverton State: OR Zip: 97008

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 503-352-3811 Website: www.northwestcompounders.com

Licensing Company Email: luke.nwc@gmail.com

Section 2: Personal Information

First: Nancy Middle: June Last: Eilers

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 14705 SW 150th Ave

City: Portland State: OR Zip: 97224

Telephone: [redacted] Email: nwcompounders@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

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Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Portland State University		9/1995	9/2000
Address 1825 SW Broadway 2000 SW 5th Ave	City Portland	State OR	Zip 97201
Diploma/Degree obtained, if any Degree in social science completed			

School Name		From - To (MM/YY – MM/YY)	
Lincoln High School		09/71 - 6/75	
Address 1750 SW Salmon St	City Portland	State OR	Zip 97205
Diploma/Degree obtained, if any yes graduated			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/16 - current	[redacted]	Portland	OR	97224
10/65 - 1/16	[redacted]	Lake Os	OR	97035
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Payless Compounders LLC DBA NW Compounders			10/5 - Current
Business Address	**City**	**State**	**Zip**
9505 SW Creekside	Beaverton	OR	97008
Phone	**Title**		
503 352 3611	member - LLC		
Description of Duties			
member LLC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

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I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nancy Eilers
Print Name (First, Last)

Mary J Eil
Original Signature (electronic, copies or stamps not accepted)

2/09/24
Date

Please have this section completed in the presence of a Notary Public.

State of Oregon, ss. County of Washington

I, Nancy June Eilers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mary J Eil
Original Signature

2/9/24
Date

Subscribed and Sworn to before me this 9th day of February.

R
Notary Public Signature

OFFICIAL STAMP
RANITHY KABO BEN
NOTARY PUBLIC - OREGON
COMMISSION NO. 1034697
MY COMMISSION EXPIRES MARCH 05, 2027

(Seal)

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2022 COMPOUNDING INSPECTION REPORT

Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland, OR 97232
(971)-673-0001
Fax: (971)-673-0002
Pharmacy.compliance@bop.oregon.gov

Compliance Officer	Laura Elvers
Date Inspection performed	10/20/22
PIC Name & License #	Luke Eilers RP-14321
PIC Work email	Luke.nwc@gmail.com
Pharmacy Name	NORTHWEST COMPOUNDERS RP-0002270
Pharmacy Address	8505 SW Creekside Place Suite 110 Beaverton, OR 97008
Pharmacy Telephone	503-352-3811
Pharmacy Fax	503-624-0591
Institutional Outlet Registration #	n/a
Retail Outlet Registration #	RP-0002270
DEA Registration # and Exp Date	BP9443956 exp 3/31/23
Drug Take Back Kiosk (Y/N)	N
RPh participating in inspection:	PIC Luke
Other staff (Name/Title) participating in inspection:	As needed- named throughout report

General Requirements

		Rule Reference	Observations
1	Does the pharmacy have access to current USP Chapters? Please list sterile and nonsterile compounding references available for staff use:	OAR 855-041-1035	PIC marked yes- USP Compounding Compendium
2	Does the pharmacy have a compounding accreditation? (Examples: VPP, PCAB, Joint Commission-Medication Compounding Certification) If yes, please specify: Date of the last accreditation: ***Please attach copy of accreditation report to this form.***		PIC marked no
3	What type of compounding is performed? Please check all that apply: Nonsterile: ☐ HRT ☐ veterinary ☐ pain creams ☐ other: Sterile: ☐ IV's ☐ TPN ☐ eye drops ☐ pellets ☐ intrathecal ☐ lyophilization ☐ other:		Nonsterile HRT, vet, pain creams and many others Sterile eye drops Some HD
4	Does the pharmacy provide sample(s) of compounded products to prescriber(s) or	OAR 855-060-0001 OAR 855-045-0210	No, but does have FDA manufacturing license

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		Rule Reference	Observations
	compound products to be sold OTC?		
5	Does the pharmacy have policies and procedures for **initial and ongoing** training and testing of all personnel according to the type of compounding performed? Are the current policies and procedures compliant with all applicable USP Chapters and Oregon laws and rules? Note: All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties. Where are the records located?	OAR 855-045-0220 OAR 855-045-0270	CO observed initial and ongoing for techs M and S RPH- Sam and Jesse Techs A and T and Jacob
6	Describe supervision of the compounding process in the pharmacy: Note: A technician may only compound under the direction, supervision and control of a pharmacist.	ORS 689.486(6)	Yes, RPh can see through windows. Also have mid-point checks for most compounds
7	Does the pharmacy have standard operating policies and procedures for cleaning, testing and calibration of all equipment and devices?	OAR 855-045-0220 OAR 855-045-0270	PIC indicated yes

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		Rule Reference	Observations
8	Does the pharmacy have standard operating policies and procedures for establishing beyond-use dates (BUDs) for compounded products? Where are the records located?	OAR 855-045-0220	PIC indicated yes- USP binder
9	Does the pharmacy handle hazardous drugs (HD's)? Is the pharmacy currently in compliance with USP 800? If so, where are the policies and procedures located? If not, what is the anticipated date of compliance? _____ Note: Handling HDs includes, but is not limited to, the receipt, storage receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.	OAR 855-045-0200 USP 800	Yes, respirators and separate USP 800 room
10	Does the pharmacy extend any BUD's beyond USP standards? If so, please describe the QA process to ensure sterility and/or stability are maintained: How often are samples sent for testing to an independent laboratory?	OAR 855-045-0220	Stability Indicating Assay Weekly

1575

		Rule Reference	Observations
	Note: The products must be tested to account for the facility's unique processes.		
11	Does the pharmacy batch compounded products? Where are the standard operating policies and procedures, including date of last documented review?		Yes, SOP binder
12	Do bulk drug substances have the required certificate of analysis? Are bulk drug substances acquired only from Board registered manufacturers or wholesalers?	e-CFR 503A Guidance Document 503B Guidance Document	yes
13	Is the pharmacy only using active pharmaceutical ingredients (API's) that are approved for use in humans?	e-CFRs	Yes, CO observed 2 shelving units of drugs – Medisca and PCCA
14	Do the master formulation records include all required elements? To include, when appropriate: • The name, strength and dosage form of the preparation; • Physical description of the final preparation; • Ingredient identities and amounts; • Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;	OAR 855-045-0270	CO reviewed acepromazine, budesonide, carprofen

1576

		Rule Reference	Observations
	• Calculations needed to determine and verify quantities of components and doses of ingredients; • Compatibility and stability information, including references; • BUD assignment and storage requirements, including reference source; • Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration; • Quality control procedures and expected results; and • Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate. Be prepared to provide documentation at the time of inspection.		
15	Do completed compounding records include all required elements? • Drug name, strength, and dosage form of the preparation; • Physical description of the final preparation, when dispensed to a patient for self-administration;	OAR 855-045-0270	CO reviewed 3 CR's as being verified by RPh

1577

		Rule Reference	Observations
	• Master formulation record reference for the preparation, when applicable; • Quantity prepared; • Date and time prepared; • Pharmacy unique lot number; • Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient; • BUD; • Pharmacist documented verification of order accuracy; • Identity of all personnel involved in each step of the process; • Documentation of the proper weight and measurement of each ingredient; • Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used; • Total quantity compounded; • BUD assignment and storage requirements, including reference source, if differs from		

1578

		Rule Reference	Observations
	master formulation record; • Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure; • Records of dispensing or transfer of all compounded preparations; and • Any other information required by the pharmacy's policies and procedures		
16	How does the pharmacy retain the identity of all personnel involved in each step of the compounding process?	OAR 855-045-0270	Compounding record
17	How does the pharmacy retain documentation of the proper weight/measurement of each ingredient of a compounded product?	OAR 855-045-0270	Printed scale weights attached to compounding worksheet CO reviewed 3
18	Does the pharmacist document verification of compounded product accuracy, including correct formula, calculations, and use of correct drugs and measurements?	OAR 855-045-0270 ORS 689.486(6)	yes
19	Does the pharmacy have policies and procedures for adverse event reporting and recalls, to include notification to the Board within 10	OAR 855-045-0220 OAR 855-045-0270	SOP handbook

1579

		Rule Reference	Observations
	working days in the event of a patient-level recall of a compounded drug? Where are the policies and procedures and records located?		
20	Does the pharmacy have policies and procedures for continuous quality assurance/quality controls? Where are documentation records located?	OAR 855-045-0200 OAR 855-045-0270	QA binder

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Compounded Sterile Products (CSP's)

		Rule Reference	Observations
21	Are CSP's prepared in an ISO 5 certified Primary Engineering Control (PEC)?	OAR 855-045-0200	Microtechnology- October 2022
22	Are all ISO classified areas checked and certified per USP guidelines every 6 months and whenever a PEC is relocated, or the physical structure of the buffer room or anteroom has been altered?	OAR 855-045-0220	yes
23	Is ISO determination taken under dynamic conditions while simulated compounding is occurring?	OAR 855-045-0200	yes
24	Are surfaces and equipment in buffer room and anteroom nonporous, smooth, non-shedding, impermeable, cleanable and resistant to disinfectants?	OAR 855-045-0200	yes

		Rule Reference	Observations
25	Does the pharmacy have policies and procedures that routinely monitor the compounding environment for microbial or fungal growth? Where are the policies and procedures and records located?	OAR 855-045-0220 OAR 855-045-0270	Yes, Policies and procedures. No growth in new compounding rooms yet
26	Does the pharmacy perform surface sampling? How often?	OAR 855-045-0220 OAR 855-045-0270	Yes, every other month
27	How often does the pharmacy test **all** compounding personnel, including verifying pharmacists, in aseptic manipulative skills, gowning and garbing and gloved fingertip sampling?	OAR 855-045-0220 OAR 855-045-0270	Q 6 months CO reviewed for techs J, S and T CO reviewed for RPh J and S
28	Do compounding procedures include requirements for use of gowns, shoe covers, hair covers, sterile gloves and masks?	OAR 855-045-0220 OAR 855-045-0200	CO observed garb, gloves and respirators. No makeup or jewelry
29	Does the pharmacy document environmental monitoring to ensure that the compounding environment is properly maintained, including temperature, humidity and pressure differential?	OAR 855-045-0270	yes
30	In addition to regular labeling requirements, does a CSP label include?	OAR 855-045-0240	CO reviewed tacrolimus

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		Rule Reference	Observations
	• The generic or official name of each active ingredient; • The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation; • The dosage form and route of administration; • Rate of infusion, for a sterile parenteral preparation; • The total quantity of the drug product; • A BUD, compliant with current USP standards; and • Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.		
31	How does the pharmacy retain documentation of the pharmacist's verification of finished CSP's? Note: There is a 3-year requirement for record retention.	OAR 855-045-0270	Paper worksheet
32	In ISO 7 and 8 areas, are floors and work surface areas cleaned daily and are walls, ceilings and shelving cleaned at least monthly? Where are the records kept?	OAR 855-045-0200	CO reviewed Oct, Sept and Aug 2022

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		Rule Reference	Observations
33	Are staff, including nonpharmacy personnel, that perform cleaning and disinfecting in ISO classified areas trained in accordance with USP? Where are these training records kept?	OAR 855-045-0220 OAR 855-045-0270	Training binder
34	What products are used to clean and disinfect? How often? Is the disinfectant a germicidal detergent? What sporicidal is used?	OAR 855-045-0220 OAR 855-045-0270	Sterile 70%, IPA, peridox Daily/weekly and in between compounds All in date

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Compliance Officer: Laura Elvers, RPh Date: 10/20/2022

Compliance Officer Notes:
See retail inspection report for additional notes. See photos at the bottom of the retail inspection report.
Q14- OAR 855-045-0270- Ensure MFR's have current references with accurate BUD per USP. (updating again 11/2023)
Inspection Completion
Pass with Notes ☐
The observations noted in this Inspection Report are not intended to be an all-inclusive list. All licensees and the registrant are responsible for complying with state and federal laws and regulations governing the practice of pharmacy.

2022 RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY INSPECTION REPORT	
Oregon Board of Pharmacy 800 NE Oregon St, Suite 150 Portland, OR 97232 (971)-673-0001 Fax: (971)-673-0002 Pharmacy.compliance@bop.oregon.gov	
Compliance Officer	Laura Elvers
Date Inspection performed	10/20/22
PIC Name & License #	Luke Eilers RP-14321
PIC Work email	luke@nwc@gmail.com
Pharmacy Name	NORTHWEST COMPOUNDERS RP-0002270
Pharmacy Address	8505 SW Creekside Place Suite 110 Beaverton, OR 97008
Pharmacy Telephone	503-352-3811
Pharmacy Fax	503-624-0591
Retail Outlet Registration #	RP-0002270
Institutional Outlet Registration #	n/a
DEA Registration # and Exp Date	BP9443956 exp 3/31/23
Nonprescription Drug Outlet #	n/a
Drug Take Back Kiosk: Y/N	N
RPh participating in inspection:	PIC Luke
Other staff (Name/Title) participating in inspection:	As needed- named throughout report

Public Health Emergency (PHE) and COVID

		Rule Reference	Observations
3	Are staff wearing masks or appropriate face coverings per current OHA requirements?	OAR 855-007-0088 OAR 333-019-1011 OAR 333-019-1025	☒Pharmacy staff is wearing masks appropriately ☐Pharmacy staff is **not** wearing masks appropriately Details: Not open to public, staff wear masks when compounding and working the front desk

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General Requirements

		Rule Reference	Observations
5	How many hours (weekly average) does the PIC work on site?	OAR 855-041-1010(1)	PIC documented on self-inspection form that they work 40 hours per week
6.	How many pharmacies is the PIC responsible for?	OAR 855-019-0300	PIC documented on self-inspection form they are PIC of 1 location ☐Quarterly report form required and reviewed ☒Quarterly report not required Details:
7	Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615	☒Licenses and registrations information accurate and up to date ☐Licenses and registration information missing Details: Idaho, Alaska and Washington

Minimum Equipment, Procedures and Records

		Rule Reference	Observations
12	Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet?	OAR 855-041-1040	PIC documented on self-inspection form they reviewed with staff on 2/1/22 date ☒Policies and Procedures reviewed annually ☐Policies and Procedures **NOT** reviewed with in past year Details:
13	Is the pharmacy clean (refrigerator, sink, reconstitution	OAR 855-041-1015(2)	☒Pharmacy is clean ☐Pharmacy is **NOT** clean

		Rule Reference	Observations
	equipment, ventilation ducts, etc.)?		Details and Images:
14	Does the pharmacy quarantine outdated, adulterated, misbranded, and suspect product?	OAR 855-041-1025 OAR 855-041-1036(1)(d)	☒None observed ☐Observed outdated, adulterated, misbranded or suspect drug product Details:
16	Is the pharmacy registered with the DEA as an authorized collector for drug take back disposal?	OAR 855-041-1046	☒N/A do not have drug take back disposal ☐Have drug take back disposal and **no** observations made ☐Have drug take back disposal and observations are made (see details) Details:
19	Is the pharmacy providing nonprescription pseudoephedrine and ephedrine to patients over the counter?	OAR 855-080-0026	☒N/A do not sell OTC pseudoephedrine ☐ Sell OTC pseudoephedrine and **no** observations made ☐ Sell OTC pseudoephedrine and observations are made (see details) Details and images:
20	Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent? If not, what is the anticipated date of compliance? Note: The prescription must bear a label in **both** English and the language requested.	OAR 855-041-1132 ORS 689.564	☒ **No** observations made ☐ Observations are made (see details) Details and images: No patients have requested this service yet
21	Does the pharmacy have signage that provide patient notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services,	OAR 855- 041-1035 (1)(e)(B)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

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		Rule Reference	Observations
	including translated prescription labels?		
22	How is the public notified that prescription readers are available at the pharmacy? How does the pharmacy provide prescription readers for visually impaired patients?	ORS 689.561	☒ **No** observations made ☐ Observations are made (see details) Details and images: PIC still working on P&P for this. No patients have requested this service yet.

Controlled Substances

		Rule Reference	Observations
24	Is the pharmacy identifying and CLEARLY DOCUMENTING AND EXPLAINING ALL VARIANCES on CII reconciliations? Note: The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least quarterly. **Note**: Providing the count at the time of the reconciliation is not sufficient to meet this requirement. **Working copies or documentation** showing the audit **and all variance explanations** for all CIIs must be kept and will be requested for review at time of inspection.	OAR 855-019-0300(5)(e)(h)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO reviewed morphine powder and hydroco/homatropine Reviewed May and August
27	Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory?	OAR 855-080-0070	☒ **No** observations made ☐ Observations are made (see details) Details and images: Annual May, moved in Oct.

		Rule Reference	Observations
29	How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?	OAR 855-041-1020	☒ **No** observations made ☐ Observations are made (see details) Details and images:

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Security

		Rule Reference	Observations
30	When no pharmacist is physically present in the pharmacy, are computers, records and medications properly secured to prevent entry and access to records by non-pharmacist employees?	OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Support Personnel

		Rule Reference	Observations
32	Are pharmacists, interns, technicians, and clerks clearly identified as such to the public?	OAR 855-025-0025(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images:
33	Is there documentation of initial and ongoing technician training? Where are the records located? Be prepared to retrieve documentation of training for ALL technicians when requested by a Board Compliance Officer.	OAR 855-025-0025(6)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO reviewed M and S
34	Do technicians know they cannot communicate with patients in terms of drug class	OAR 855-025-0040(3)(e)	☒ **No** observations made ☐ Observations are made (see details)

	or indication/use (such as when a patient asks for a refill of their "diabetes medication")? Note: Technicians can only communicate in terms of drug name and prescription number. **Pharmacists may not allow technicians to counsel, answer a patient's medication related questions, or allow a technician to relay information on their behalf.**	OAR 855-019-0200(2)(3) OAR 855-019-0230	Details and images: CO talked with Natasha- She stated she gets an RPh for anything clinical such as side effects or how to give with food. But will point out things like refills and expiration date on the bottle when asked.
35	Is each technician under the supervision, direction and control of a pharmacist and does the pharmacist verify work performed by technicians and document this verification?	ORS 689.486(6) OAR 855-025-0025(4)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Pharmacists

		Rule Reference	Observations
36	Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration? How is a DUR performed? Please provide the following details: At which point in the process does a pharmacist perform a DUR? Does this process vary depending on the type of fill (new vs refill)? How is a DUR documented?	OAR 855-019-0220(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images: Done during rx processing

1589

		Rule Reference	Observations
	Note: A Pharmacist must perform a DUR on each fill (the computer may assist but does not replace RPH)		
38	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	OAR 855-019-0220(1) OAR 855-041-1165	☒ **No** observations made ☐ Observations are made (see details) Details and images: 5/5
39	Does the PIC ensure that policies and procedures are followed to ensure that prescriptions are correctly dispensed?	OAR 855-041-1105	☒ **No** observations made ☐ Observations are made (see details) Details and images: 5/5
41	Does the pharmacist document verification of '**return to stock**' medications **re-labeled** by a technician or intern?	OAR 855-025-0025(4) OAR 855-019-0200	☒ **No** observations made ☐ Observations are made (see details) Details and images:
42	Is a pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?	OAR 855-019-0200(2) OAR 855-041-1130(10)	☐ **No** observations made ☒ Observations are made (see details) Details and images: CO observed 1 magic mouthwash with 35 day BUD. (photos) Rx 513357

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		Rule Reference	Observations
			Prepared 10/20/22, BUD 11/24/22  
45	How is a new prescription identified as requiring counseling?	OAR 855-019-0230	☒ **No** observations made ☐ Observations are made (see details) Details and images:
47	Is the pharmacist/intern (not a patient/clerk/technician or point-of-sale keypad) personally documenting whether counseling is provided or declined on prescriptions that require counseling **at the time** of the counseling?	OAR 855-019-0230(1)(c)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Drug Storage

		Inspection Review	Rule Reference	Observations
48	Does each active cold storage system maintain the temperature of refrigerated products between 2-8°C (35-46°F) and frozen products between -25 to -10°C (-		OAR 855-041-1036 (2)(a)(A)	☐ **No** observations made ☒ Observations are made (see details) Details and images:

1591

		Inspection Review	Rule Reference	Observations
	13 to 14°F) **or as specified by the manufacturer?** Note: An excursion is **any** temperature outside of these specified parameters. **Each excursion requires a detailed written explanation in accordance with the requirements of this rule.**			March- no excursions June16th Lab fridge 1 8.26 degrees June 3 and 4 = 9.1 peak conf fridge Sept- 20th lab 1 fridge excursion 20th 8.57 Sept 12th lab 1 fridge max 8.43 Excursions: 4/25- min 0.8 conf fridge 6/4- max 9.1 conf fridge 7/11-15- lab fridge- max 8.95 7/19-conf fridge max 9.8 8/5-conf fridge max 9.3 8/23 and 24- lab 1 fridge max 9.5 10/4-6- lab 1 fridge max 9.06 10/6- will call freezer max 0.2 C (sheet states temps to be between negative 25C to negative10 C) 0.2 C= 32.36 F
49	Are the thermometers/probes centrally placed, accurate and calibrated? When is the next calibration (to ensure temperature readings are correct) due?		OAR 855-041-1036(2)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO saw calibration docs in date
51	**Explanation and documentation of ALL drug storage excursions must include at least all the following:** • The event date & time frame; • The name of person(s) involved in response; • How long drug(s)/vaccine(s) were out of range; • Temperature variances;		OAR 855-041-1036(2)(b) (D-E)	☐ **No** observations made ☒ Observations are made (see details) Details and images: June16th Lab fridge 1 8.26 degrees June 3 and 4 = 9.1 peak conf fridge Sept- 20th lab 1 fridge excursion 20th 8.57, Sept 12th lab 1 fridge max 8.43 Excursions: 6/4, 7/11-15, 7/19, 8/5, 8/23-24, 10/4-6.

1592

		Inspection Review	Rule Reference	Observations
	• Pharmacist review of duration and variance; • The decision to quarantine for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; • Which pharmacist made the final decision; • The information resource used to determine whether drug/vaccine is safe for continued use.			PIC response 10/21/2022 9/12/22- less than 12 hours 0.57 degrees- form completed 6/16/22- less than 12 hours 0.26 degrees C- form completed 6/3/22- less than 12 hours, 1.1 degrees. Form completed Excursions: 6/4, 7/11-15, 7/19, 8/5, 8/23-25, 9/20, 10/4-6- no excursion form provided.

1593

Vaccine Drug Storage ☒ N/A

		Rule Reference	Observations
53	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator?	OAR 855-041-1036(3) (a)(A)	☐ **No** observations made ☐ Observations are made (see details) Details and images:
55	Does the pharmacy conduct quarterly **validations** of **EACH** *vaccine* storage unit and their monitoring equipment?	OAR 855-041-1036(3) (a)(D)	☐ **No** observations made ☐ Observations are made (see details) Details and images:

Vaccine Administration ☒ N/A

Prescriptive Authority is per OHA vaccine protocol

Rule Reference	Observations

56	Do all immunizing pharmacists/interns have a current CPR card intended for healthcare providers? Is the CPR training applicable for the age of patient's staff are vaccinating?	OAR 855-019-0270 OAR 855-019-0290(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images:
57	Does the pharmacy have required equipment and supplies for managing adverse events and are reviews done to ensure all supplies are readily retrievable and that no medication will expire before the next review?	OAR 855-019-0270	☒ **No** observations made ☐ Observations are made (see details) Details and images:
58	Does each pharmacist have access to ALERT and utilize it to perform a DUR and forecast potential immunizations?	OAR 855-019-0290	☒ **No** observations made ☐ Observations are made (see details) Details and images
59	Is the pharmacist/intern who administers any vaccine/immunization recording and maintaining the required information?	OAR 855-019-0290	☒ **No** observations made ☐ Observations are made (see details) Details and images

Collaborative Drug Therapy Management (CDTM) ☒ N/A

		Rule Reference	Observations
60	Do pharmacists participate in Collaborative Drug Therapy Management (CDTM) agreements?	OAR 855-019-0260	no
61	Does the written CDTM agreement contain the required details?	OAR 855-019-0260 (2)(a-g) and (3)	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: (Public Health & Pharmacy Formulary Advisory Committee) ☒N/A

1594

		Rule Reference	Observations
64	Do pharmacists at this location prescribe and dispense FDA approved drugs and devices included on either the Formulary or Protocol Compendia?	OAR 855-020-0200 OAR 855-020-0300 OAR 855-020-0120	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Contraceptive: ☒N/A

		Rule Reference	Observations
67	Do pharmacists at this location prescribe hormonal contraceptives?	OAR 855-019-0425 OAR 855-019-0430 OAR 855-019-0435	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Naloxone ☒ N/A

		Rule Reference	Observations
69	Do pharmacists at this location prescribe naloxone?	OAR 855-019-0460 OAR 855-041-2340	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Emergency Insulin and Supplies ☒ N/A

		Rule Reference	Observations
70	Have any pharmacists completed a Board approved ACPE accredited training program to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices?	OAR 855-019-0470	☒ **No** observations made ☐ Observations are made (see details) Details and images

Telework ☒N/A

1595

		Rule Reference	Observations
71	Do pharmacy staff (Pharmacists, Interns or COPT) work from a location physically outside of the pharmacy (i.e., their home)?	OAR 855-041-3205	no
73	How does the PIC and Pharmacists ensure the supervision, direction, and control of COPTs? And that No drugs or Devices are permitted at telework sites?	OAR 855-041-3215 OAR 855-041-3220	☒ **No** observations made ☐ Observations are made (see details) Details and images
75	Does the pharmacy maintain a continuously updated list of all licensees engaged in telework and the Telework Sites that includes all of the following: • Address and phone number where telework is performed for each Telework Site? • Functions being performed by licensees engaged in telework? • The Pharmacist providing supervision, direction, and control for each non-pharmacist licensee?	OAR 855-041-3215 OAR 855-041-3250	☒ **No** observations made ☐ Observations are made (see details) Details and images
76	Are all of the supervision requirements met?	OAR 855-041-3220	☒ **No** observations made ☐ Observations are made (see details)
77	Are all of the supervision requirements met by the Pharmacist?	OAR 855-041-3220	
78	How does the pharmacy ensure patient confidentiality?	OAR 855-041-3225 OAR 855-041-3240	☒ **No** observations made ☐ Observations are made (see details) Details and images
79	Is a COPT or Intern able to access the pharmacy and patient information when a pharmacist is not actively supervising?	OAR 855-041-3240	☒ **No** observations made ☐ Observations are made (see details) Details and images
80	Are the technology requirements met?	OAR 855-041-3230	☒ **No** observations made ☐ Observations are made (see details) Details and images
81	If a pharmacist is performing verification via telework, are all of the requirements met?	OAR 855-041-3230(1)	☒ **No** observations made ☐ Observations are made (see details) Details and images

1596

		Rule Reference	Observations
82	Does each Pharmacist determine and document how many licensed individuals they are capable of supervising, directing, and controlling?	OAR 855-041-3235	☒ **No** observations made ☐ Observations are made (see details) Details and images

Long Term Care (LTC) / Community Based Care (CBC) Services ☒ N/A

		Rule Reference	Observations
86	Is the pharmacy ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-6310 AND that there is a practitioner's order to authorize the removal of medications?	OAR 855-041-7060(2)(b) OAR 855-041-7060(5)	☐ **No** observations made ☐ Observations are made (see details) Details and images
87	If the pharmacy accepts the return of previously dispensed prescriptions, is the facility in compliance with OAR 855-041-1045?	OAR 855-041-1045	☐ **No** observations made ☐ Observations are made (see details) Details and images
90	Are all partially dispensed CII prescriptions (Note: Valid for up to a maximum of 60 days from the date written) documented with the required information?	21 CFR 1306.13	☐ **No** observations made ☐ Observations are made (see details) Details and images

☒Pharmacy Performs Compounding: please see completed pharmacy Compounding Inspection Report

Laura Elvers **10/20/22**

Compliance Officer Date

***Completed Inspection Report must be maintained for 3 years along with completed Self Inspection Report Forms**

Compliance Officer Notes:
Q20 and 22- Translated labels and prescription reader availability. PIC resolved 10/21/2022
Q51- OAR 855-041-1036(2)(b) (D-E) Temperature excursion documentation missing for excursions on 6/4, 7/11-15, 7/19, 8/5, 8/23-25, 9/20, 10/4-6.

1597

Inspection Completion
PASS WITH NOTES
The observations noted in this Inspection Report are not intended to be an all-inclusive list. All licensees and the registrant are responsible for complying with state and federal laws and regulations governing the practice of pharmacy.

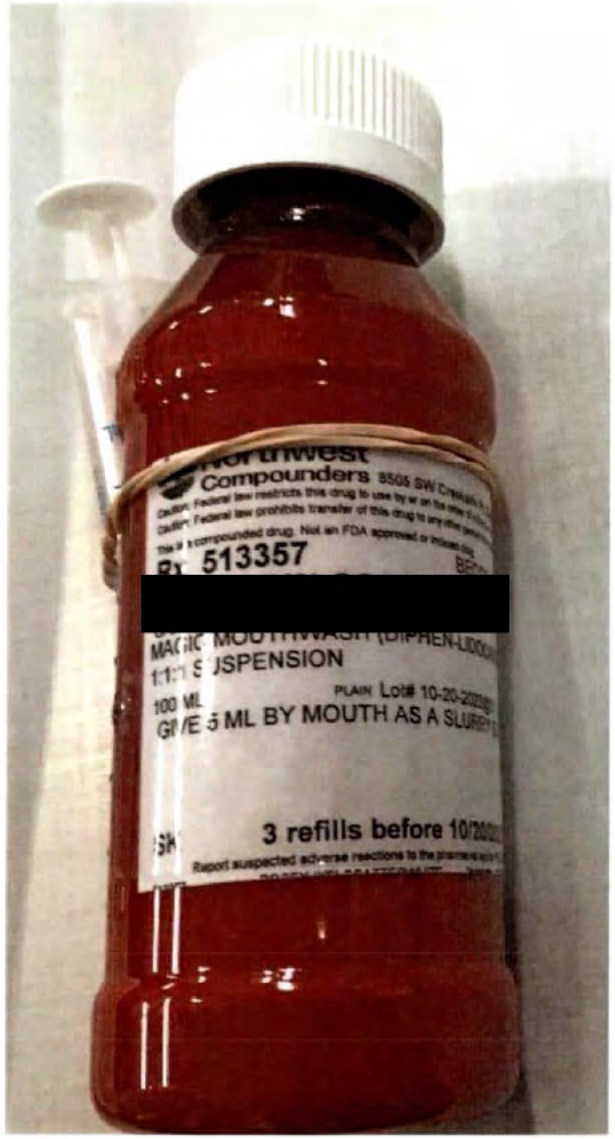
IMAGES: (Question #, description)

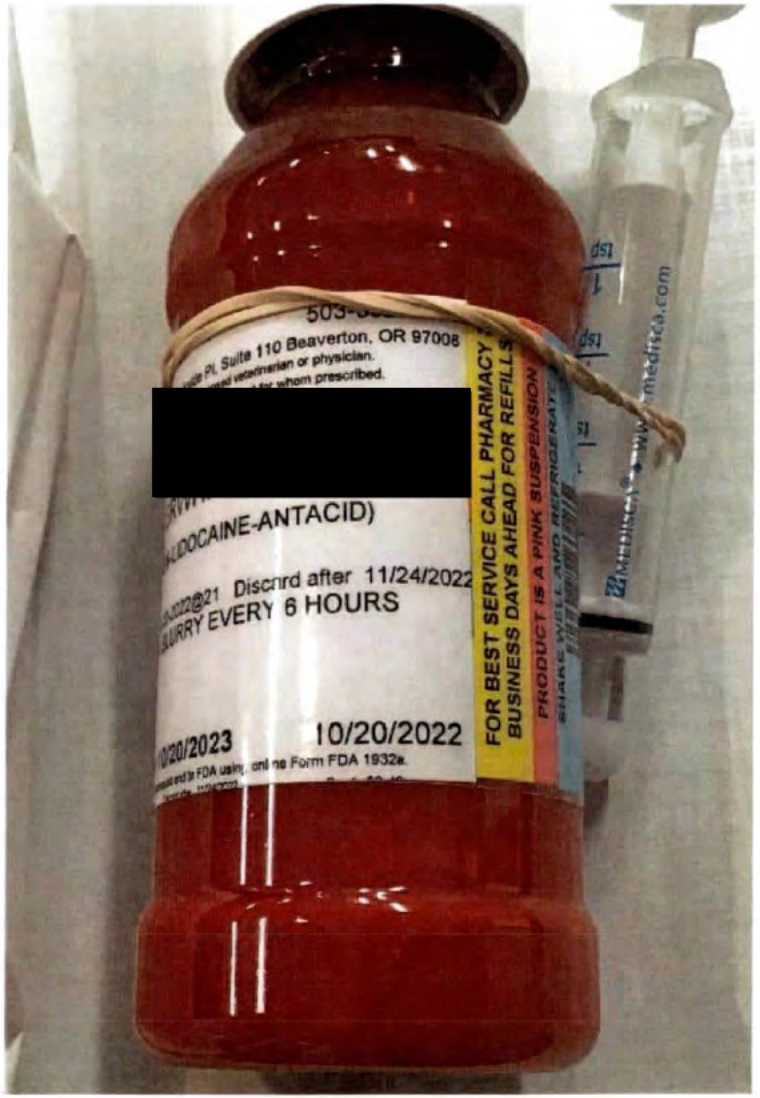

Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems


iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems

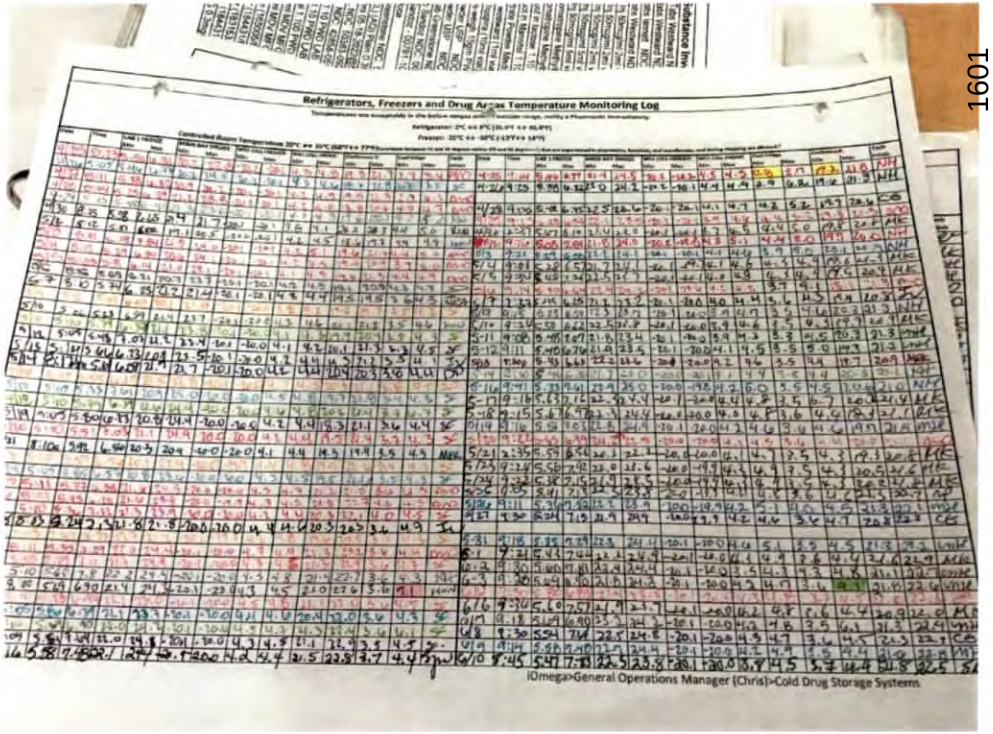

Freezers and Drug Areas Temperature Monitoring Log
Refrigerator: 2°C ↔ 8°C (35.6°F ↔ 46.4°F)
Freezer: -25°C ↔ -10°C (-13°F↔ 14°F)


Freezers and Drug Areas Temperature Monitoring Log
Refrigerator: 2°C ↔ 8°C (35.6°F ↔ 46.4°F)
Freezer: -25°C ↔ -10°C (-13°F↔ 14°F)

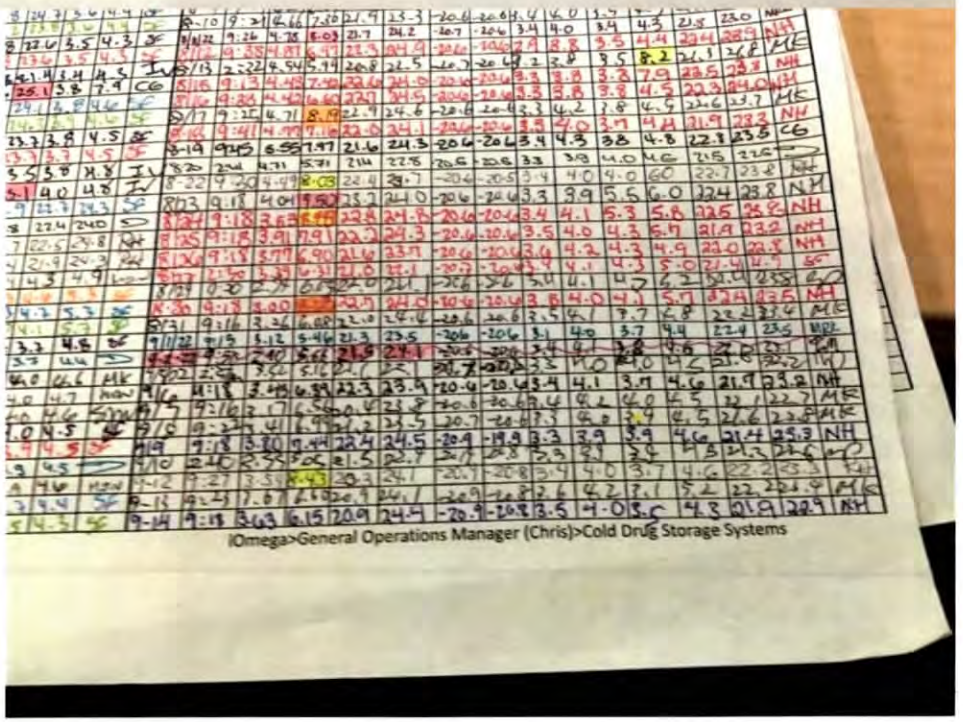

Compounders
513357
SUSPENSION
PLAIN
GIVE 5 ML BY MOUTH AS A SLURP
3 refills before


Suite 110 Beaverton, OR 97008
LIDOCAINE-ANTACID)
Discard after 11/24/2022
SLURRY EVERY 6 HOURS
10/20/2023
10/20/2022
FOR BEST SERVICE CALL PHARMACY
BUSINESS DAYS AHEAD FOR REFILLS
PRODUCT IS A PINK SUSPENSION


Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems


Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems

1601


iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems

1602

2022 RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY INSPECTION REPORT	
Oregon Board of Pharmacy **800 NE Oregon St, Suite 150** **Portland, OR 97232** **(971)-673-0001** **Fax: (971)-673-0002** **Pharmacy.compliance@bop.oregon.gov**	
Compliance Officer	Laura Elvers
Date Inspection performed	10/20/22
PIC Name & License #	Luke Eilers RP-14321
PIC Work email	luke@nwc@gmail.com
Pharmacy Name	NORTHWEST COMPOUNDERS RP-0002270
Pharmacy Address	8505 SW Creekside Place Suite 110 Beaverton, OR 97008
Pharmacy Telephone	503-352-3811
Pharmacy Fax	503-624-0591
Retail Outlet Registration #	RP-0002270
Institutional Outlet Registration #	n/a
DEA Registration # and Exp Date	BP9443956 exp 3/31/23
Nonprescription Drug Outlet #	n/a
Drug Take Back Kiosk: Y/N	N
RPh participating in inspection:	PIC Luke
Other staff (Name/Title) participating in inspection:	As needed- named throughout report

Public Health Emergency (PHE) and COVID

		Rule Reference	Observations
3	Are staff wearing masks or appropriate face coverings per current OHA requirements?	OAR 855-007-0088 OAR 333-019-1011 OAR 333-019-1025	☒Pharmacy staff is wearing masks appropriately ☐Pharmacy staff is **not** wearing masks appropriately Details: Not open to public, staff wear masks when compounding and working the front desk

1603

General Requirements

		Rule Reference	Observations
5	How many hours (weekly average) does the PIC work on site?	OAR 855-041-1010(1)	PIC documented on self-inspection form that they work 40 hours per week
6.	How many pharmacies is the PIC responsible for?	OAR 855-019-0300	PIC documented on self-inspection form they are PIC of 1 location ☐Quarterly report form required and reviewed ☒Quarterly report not required Details:
7	Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615	☒Licenses and registrations information accurate and up to date ☐Licenses and registration information missing Details: Idaho, Alaska and Washington

Minimum Equipment, Procedures and Records

		Rule Reference	Observations
12	Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet?	OAR 855-041-1040	PIC documented on self-inspection form they reviewed with staff on 2/1/22 date ☒Policies and Procedures reviewed annually ☐Policies and Procedures **NOT** reviewed with in past year Details:
13	Is the pharmacy clean (refrigerator, sink, reconstitution	OAR 855-041-1015(2)	☒Pharmacy is clean ☐Pharmacy is **NOT** clean

		Rule Reference	Observations
	equipment, ventilation ducts, etc.)?		Details and Images:
14	Does the pharmacy quarantine outdated, adulterated, misbranded, and suspect product?	OAR 855-041-1025 OAR 855-041-1036(1)(d)	☒None observed ☐Observed outdated, adulterated, misbranded or suspect drug product Details:
16	Is the pharmacy registered with the DEA as an authorized collector for drug take back disposal?	OAR 855-041-1046	☒N/A do not have drug take back disposal ☐Have drug take back disposal and **no** observations made ☐Have drug take back disposal and observations are made (see details) Details:
19	Is the pharmacy providing nonprescription pseudoephedrine and ephedrine to patients over the counter?	OAR 855-080-0026	☒N/A do not sell OTC pseudoephedrine ☐ Sell OTC pseudoephedrine and **no** observations made ☐ Sell OTC pseudoephedrine and observations are made (see details) Details and images:
20	Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent? If not, what is the anticipated date of compliance? Note: The prescription must bear a label in **both** English and the language requested.	OAR 855-041-1132 ORS 689.564	☒ **No** observations made ☐ Observations are made (see details) Details and images: No patients have requested this service yet
21	Does the pharmacy have signage that provide patient notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services,	OAR 855- 041-1035 (1)(e)(B)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

1604

		Rule Reference	Observations
	including translated prescription labels?		
22	How is the public notified that prescription readers are available at the pharmacy? How does the pharmacy provide prescription readers for visually impaired patients?	ORS 689.561	☒ **No** observations made ☐ Observations are made (see details) Details and images: PIC still working on P&P for this. No patients have requested this service yet.

Controlled Substances

		Rule Reference	Observations
24	Is the pharmacy identifying and CLEARLY DOCUMENTING AND EXPLAINING ALL VARIANCES on CII reconciliations? Note: The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least quarterly. **Note**: Providing the count at the time of the reconciliation is not sufficient to meet this requirement. **Working copies or documentation** showing the audit **and all variance explanations** for all CIIs must be kept and will be requested for review at time of inspection.	OAR 855-019-0300(5)(e)(h)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO reviewed morphine powder and hydroco/homatropine Reviewed May and August
27	Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory?	OAR 855-080-0070	☒ **No** observations made ☐ Observations are made (see details) Details and images: Annual May, moved in Oct.

1605

		Rule Reference	Observations
29	How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?	OAR 855-041-1020	☒ **No** observations made ☐ Observations are made (see details) Details and images:

1606

Security

		Rule Reference	Observations
30	When no pharmacist is physically present in the pharmacy, are computers, records and medications properly secured to prevent entry and access to records by non-pharmacist employees?	OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Support Personnel

		Rule Reference	Observations
32	Are pharmacists, interns, technicians, and clerks clearly identified as such to the public?	OAR 855-025-0025(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images:
33	Is there documentation of initial and ongoing technician training? Where are the records located? Be prepared to retrieve documentation of training for ALL technicians when requested by a Board Compliance Officer.	OAR 855-025-0025(6)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO reviewed M and S
34	Do technicians know they cannot communicate with patients in terms of drug class	OAR 855-025-0040(3)(e)	☒ **No** observations made ☐ Observations are made (see details)

	or indication/use (such as when a patient asks for a refill of their "diabetes medication")? Note: Technicians can only communicate in terms of drug name and prescription number. **Pharmacists may not allow technicians to counsel, answer a patient's medication related questions, or allow a technician to relay information on their behalf.**	OAR 855-019-0200(2)(3) OAR 855-019-0230	Details and images: CO talked with Natasha- She stated she gets an RPh for anything clinical such as side effects or how to give with food. But will point out things like refills and expiration date on the bottle when asked.
35	Is each technician under the supervision, direction and control of a pharmacist and does the pharmacist verify work performed by technicians and document this verification?	ORS 689.486(6) OAR 855-025-0025(4)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Pharmacists

		Rule Reference	Observations
36	Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration? How is a DUR performed? Please provide the following details: At which point in the process does a pharmacist perform a DUR? Does this process vary depending on the type of fill (new vs refill)? How is a DUR documented?	OAR 855-019-0220(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images: Done during rx processing

1607

		Rule Reference	Observations
	Note: A Pharmacist must perform a DUR on each fill (the computer may assist but does not replace RPH)		
38	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	OAR 855-019-0220(1) OAR 855-041-1165	☒ **No** observations made ☐ Observations are made (see details) Details and images: 5/5
39	Does the PIC ensure that policies and procedures are followed to ensure that prescriptions are correctly dispensed?	OAR 855-041-1105	☒ **No** observations made ☐ Observations are made (see details) Details and images: 5/5
41	Does the pharmacist document verification of '**return to stock**' medications **re-labeled** by a technician or intern?	OAR 855-025-0025(4) OAR 855-019-0200	☒ **No** observations made ☐ Observations are made (see details) Details and images:
42	Is a pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?	OAR 855-019-0200(2) OAR 855-041-1130(10)	☐ **No** observations made ☒ Observations are made (see details) Details and images: CO observed 1 magic mouthwash with 35 day BUD. (photos) Rx 513357

		Rule Reference	Observations
			Prepared 10/20/22, BUD 11/24/22  
45	How is a new prescription identified as requiring counseling?	OAR 855-019-0230	☒ **No** observations made ☐ Observations are made (see details) Details and images:
47	Is the pharmacist/intern (not a patient/clerk/technician or point-of-sale keypad) personally documenting whether counseling is provided or declined on prescriptions that require counseling **at the time** of the counseling?	OAR 855-019-0230(1)(c)	☒ **No** observations made ☐ Observations are made (see details) Details and images:

Drug Storage

		Inspection Review	Rule Reference	Observations
48	Does each active cold storage system maintain the temperature of refrigerated products between 2-8°C (35-46°F) and frozen products between -25 to -10°C (-		OAR 855-041-1036 (2)(a)(A)	☐ **No** observations made ☒ Observations are made (see details) Details and images:

		Inspection Review	Rule Reference	Observations
	13 to 14°F) **or as specified by the manufacturer?** Note: An excursion is **any** temperature outside of these specified parameters. **Each excursion requires a detailed written explanation in accordance with the requirements of this rule.**			March- no excursions June16th Lab fridge 1 8.26 degrees June 3 and 4 = 9.1 peak conf fridge Sept- 20th lab 1 fridge excursion 20th 8.57 Sept 12th lab 1 fridge max 8.43 Excursions: 4/25- min 0.8 conf fridge 6/4- max 9.1 conf fridge 7/11-15- lab fridge- max 8.95 7/19-conf fridge max 9.8 8/5-conf fridge max 9.3 8/23 and 24- lab 1 fridge max 9.5 10/4-6- lab 1 fridge max 9.06 10/6- will call freezer max 0.2 C (sheet states temps to be between negative 25C to negative10 C) 0.2 C= 32.36 F
49	Are the thermometers/probes centrally placed, accurate and calibrated? When is the next calibration (to ensure temperature readings are correct) due?		OAR 855-041-1036(2)	☒ **No** observations made ☐ Observations are made (see details) Details and images: CO saw calibration docs in date
51	**Explanation and documentation of ALL drug storage excursions must include at least all the following:** • The event date & time frame; • The name of person(s) involved in response; • How long drug(s)/vaccine(s) were out of range; • Temperature variances;		OAR 855-041-1036(2)(b)(D-E)	☐ **No** observations made ☒ Observations are made (see details) Details and images: June16th Lab fridge 1 8.26 degrees June 3 and 4 = 9.1 peak conf fridge Sept- 20th lab 1 fridge excursion 20th 8.57, Sept 12th lab 1 fridge max 8.43 Excursions: 6/4, 7/11-15, 7/19, 8/5, 8/23-24, 10/4-6.

1610

		Inspection Review	Rule Reference	Observations
	• Pharmacist review of duration and variance; • The decision to quarantine for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; • Which pharmacist made the final decision; • The information resource used to determine whether drug/vaccine is safe for continued use.			PIC response 10/21/2022 9/12/22- less than 12 hours 0.57 degrees- form completed 6/16/22- less than 12 hours 0.26 degrees C- form completed 6/3/22- less than 12 hours, 1.1 degrees. Form completed Excursions: 6/4, 7/11-15, 7/19, 8/5, 8/23-25, 9/20, 10/4-6- no excursion form provided.

1611

Vaccine Drug Storage ☒ N/A

		Rule Reference	Observations
53	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator?	OAR 855-041-1036(3) (a)(A)	☐ **No** observations made ☐ Observations are made (see details) Details and images:
55	Does the pharmacy conduct quarterly **validations** of **EACH** *vaccine* storage unit and their monitoring equipment?	OAR 855-041-1036(3) (a)(D)	☐ **No** observations made ☐ Observations are made (see details) Details and images:

Vaccine Administration ☒ N/A

Prescriptive Authority is per OHA vaccine protocol

Rule Reference	Observations

56	Do all immunizing pharmacists/interns have a current CPR card intended for healthcare providers? Is the CPR training applicable for the age of patient's staff are vaccinating?	OAR 855-019-0270 OAR 855-019-0290(3)	☒ **No** observations made ☐ Observations are made (see details) Details and images:
57	Does the pharmacy have required equipment and supplies for managing adverse events and are reviews done to ensure all supplies are readily retrievable and that no medication will expire before the next review?	OAR 855-019-0270	☒ **No** observations made ☐ Observations are made (see details) Details and images:
58	Does each pharmacist have access to ALERT and utilize it to perform a DUR and forecast potential immunizations?	OAR 855-019-0290	☒ **No** observations made ☐ Observations are made (see details) Details and images
59	Is the pharmacist/intern who administers any vaccine/immunization recording and maintaining the required information?	OAR 855-019-0290	☒ **No** observations made ☐ Observations are made (see details) Details and images

Collaborative Drug Therapy Management (CDTM) ☒ N/A

		Rule Reference	Observations
60	Do pharmacists participate in Collaborative Drug Therapy Management (CDTM) agreements?	OAR 855-019-0260	no
61	Does the written CDTM agreement contain the required details?	OAR 855-019-0260 (2)(a-g) and (3)	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: (Public Health & Pharmacy Formulary Advisory Committee) ☒N/A

1612

		Rule Reference	Observations
64	Do pharmacists at this location prescribe and dispense FDA approved drugs and devices included on either the Formulary or Protocol Compendia?	OAR 855-020-0200 OAR 855-020-0300 OAR 855-020-0120	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Contraceptive: ☒N/A

		Rule Reference	Observations
67	Do pharmacists at this location prescribe hormonal contraceptives?	OAR 855-019-0425 OAR 855-019-0430 OAR 855-019-0435	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Naloxone ☒ N/A

		Rule Reference	Observations
69	Do pharmacists at this location prescribe naloxone?	OAR 855-019-0460 OAR 855-041-2340	☒ **No** observations made ☐ Observations are made (see details) Details and images

Pharmacist Prescriptive Authority: Emergency Insulin and Supplies ☒ N/A

		Rule Reference	Observations
70	Have any pharmacists completed a Board approved ACPE accredited training program to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices?	OAR 855-019-0470	☒ **No** observations made ☐ Observations are made (see details) Details and images

Telework ☒N/A

		Rule Reference	Observations
71	Do pharmacy staff (Pharmacists, Interns or COPT) work from a location physically outside of the pharmacy (i.e., their home)?	OAR 855-041-3205	no
73	How does the PIC and Pharmacists ensure the supervision, direction, and control of COPTs? And that No drugs or Devices are permitted at telework sites?	OAR 855-041-3215 OAR 855-041-3220	☒ **No** observations made ☐ Observations are made (see details) Details and images
75	Does the pharmacy maintain a continuously updated list of all licensees engaged in telework and the Telework Sites that includes all of the following: • Address and phone number where telework is performed for each Telework Site? • Functions being performed by licensees engaged in telework? • The Pharmacist providing supervision, direction, and control for each non-pharmacist licensee?	OAR 855-041-3215 OAR 855-041-3250	☒ **No** observations made ☐ Observations are made (see details) Details and images
76	Are all of the supervision requirements met?	OAR 855-041-3220	☒ **No** observations made ☐ Observations are made (see details)
77	Are all of the supervision requirements met by the Pharmacist?	OAR 855-041-3220	
78	How does the pharmacy ensure patient confidentiality?	OAR 855-041-3225 OAR 855-041-3240	☒ **No** observations made ☐ Observations are made (see details) Details and images
79	Is a COPT or Intern able to access the pharmacy and patient information when a pharmacist is not actively supervising?	OAR 855-041-3240	☒ **No** observations made ☐ Observations are made (see details) Details and images
80	Are the technology requirements met?	OAR 855-041-3230	☒ **No** observations made ☐ Observations are made (see details) Details and images
81	If a pharmacist is performing verification via telework, are all of the requirements met?	OAR 855-041-3230(1)	☒ **No** observations made ☐ Observations are made (see details) Details and images

1614

		Rule Reference	Observations
82	Does each Pharmacist determine and document how many licensed individuals they are capable of supervising, directing, and controlling?	OAR 855-041-3235	☒ **No** observations made ☐ Observations are made (see details) Details and images

1615

Long Term Care (LTC) / Community Based Care (CBC) Services ☒ N/A

		Rule Reference	Observations
86	Is the pharmacy ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-6310 AND that there is a practitioner's order to authorize the removal of medications?	OAR 855-041-7060(2)(b) OAR 855-041-7060(5)	☐ **No** observations made ☐ Observations are made (see details) Details and images
87	If the pharmacy accepts the return of previously dispensed prescriptions, is the facility in compliance with OAR 855-041-1045?	OAR 855-041-1045	☐ **No** observations made ☐ Observations are made (see details) Details and images
90	Are all partially dispensed CII prescriptions (Note: Valid for up to a maximum of 60 days from the date written) documented with the required information?	21 CFR 1306.13	☐ **No** observations made ☐ Observations are made (see details) Details and images

☒Pharmacy Performs Compounding: please see completed pharmacy Compounding Inspection Report

Laura Elvers **10/20/22**

Compliance Officer Date

***Completed Inspection Report must be maintained for 3 years along with completed Self Inspection Report Forms**

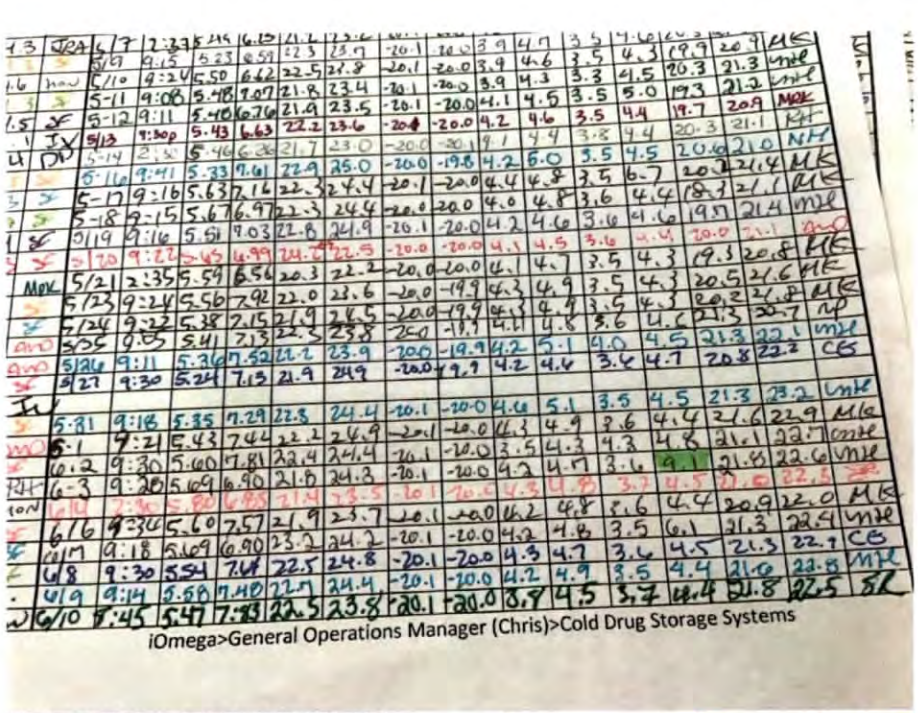
Compliance Officer Notes:
Q20 and 22- Translated labels and prescription reader availability. PIC resolved 10/21/2022
Q51- OAR 855-041-1036(2)(b) (D-E) Temperature excursion documentation missing for excursions on 6/4, 7/11-15, 7/19, 8/5, 8/23-25, 9/20, 10/4-6.

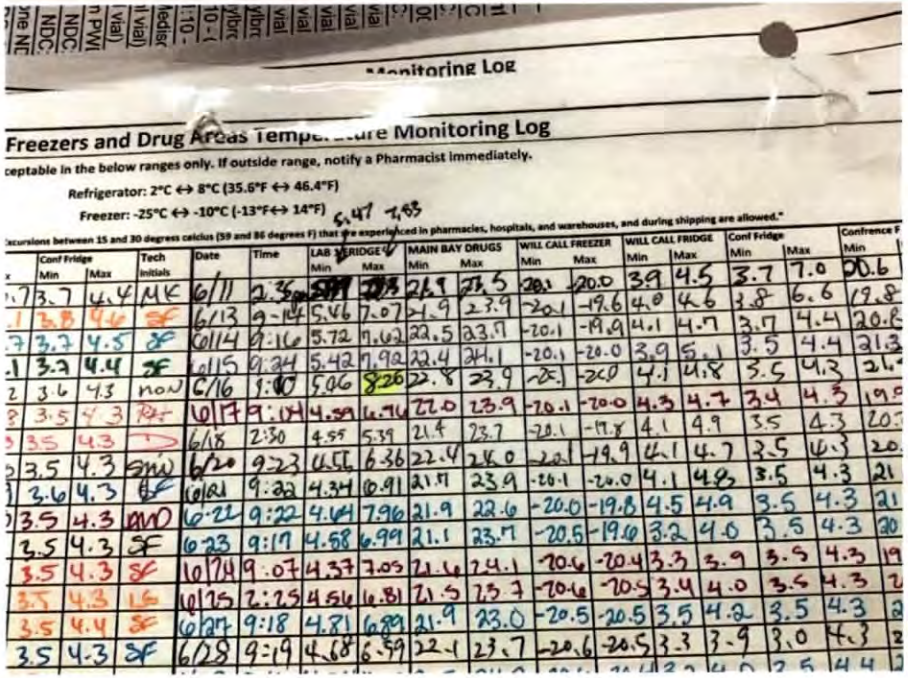
Inspection Completion
PASS WITH NOTES
The observations noted in this Inspection Report are not intended to be an all-inclusive list. All licensees and the registrant are responsible for complying with state and federal laws and regulations governing the practice of pharmacy.

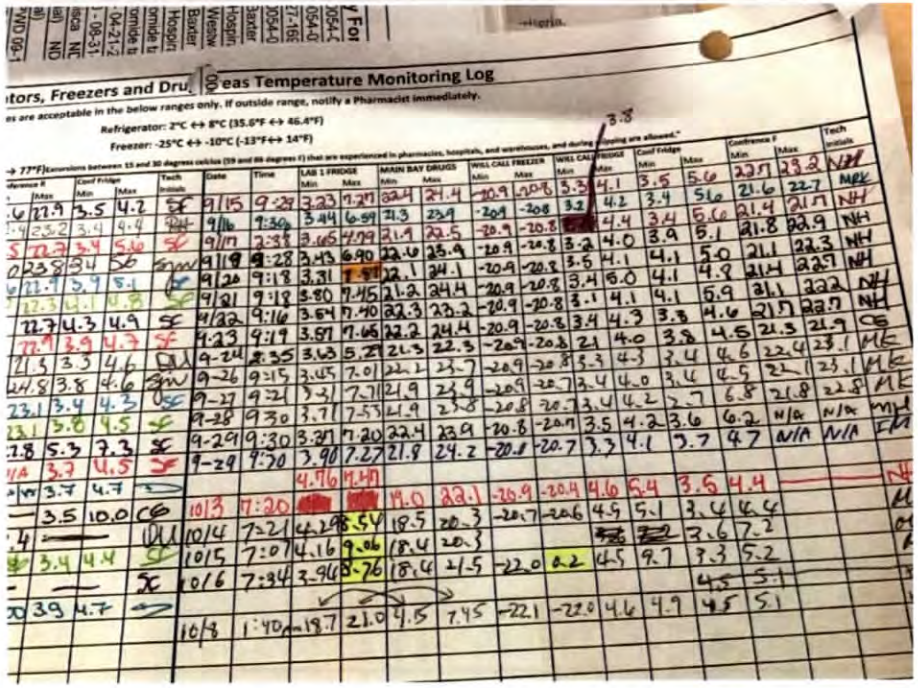
1616

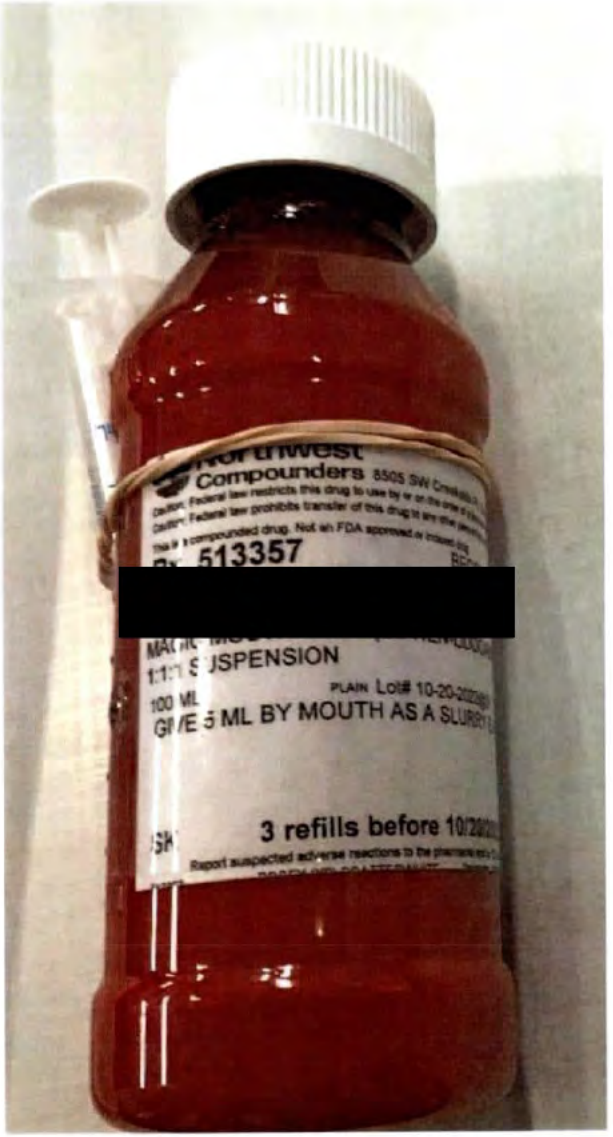
IMAGES: (Question #, description)

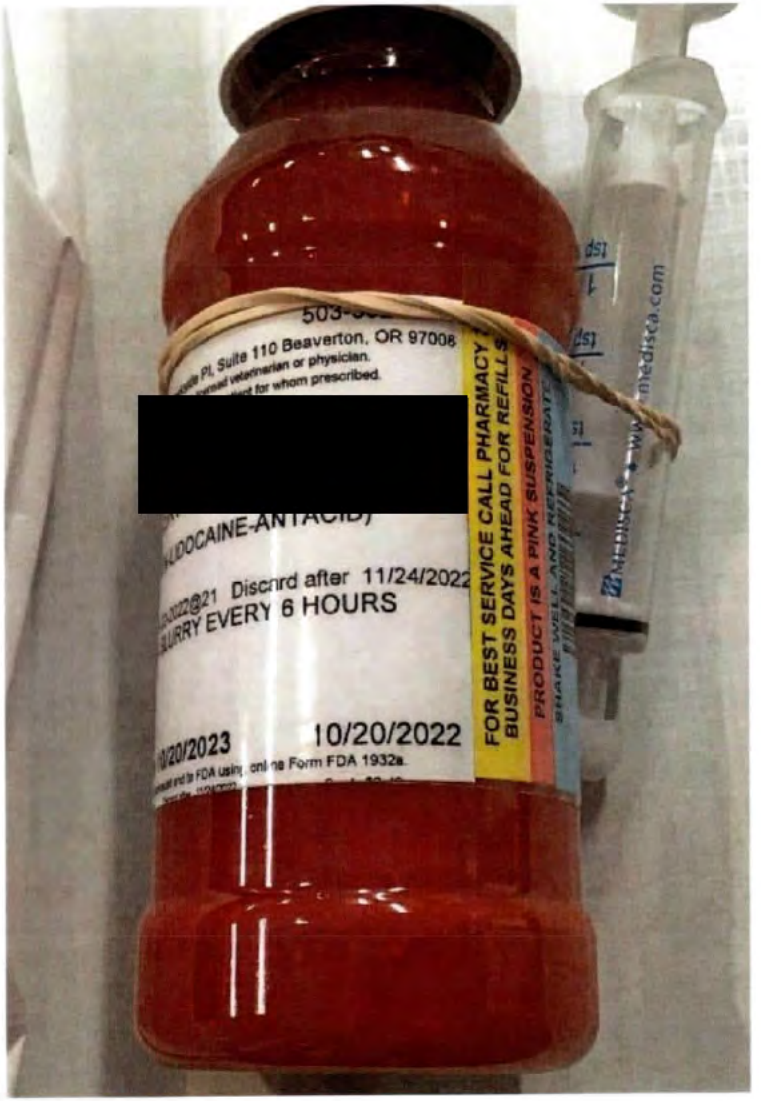

Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems


iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems

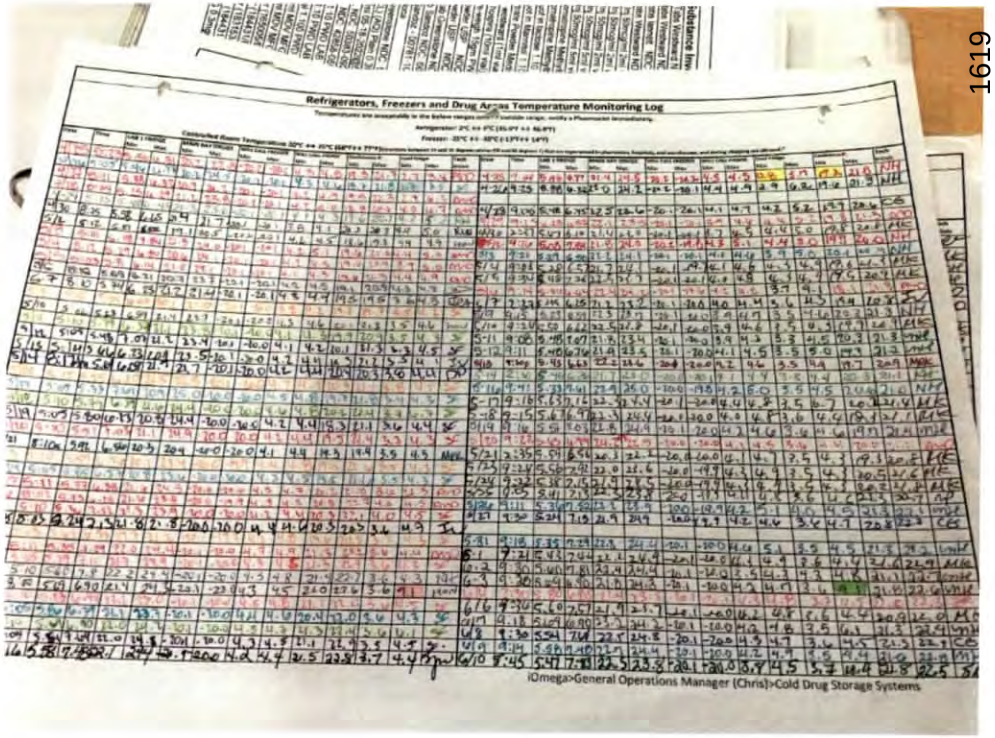

Freezers and Drug Areas Temperature Monitoring Log
Refrigerator: 2°C ↔ 8°C (35.6°F ↔ 46.4°F)
Freezer: -25°C ↔ -10°C (-13°F↔ 14°F)


Refrigerator: 2°C ↔ 8°C (35.6°F ↔ 46.4°F)
Freezer: -25°C ↔ -10°C (-13°F↔ 14°F)


Northwest
Compounders
513357
SUSPENSION
PLAIN
GIVE 5 ML BY MOUTH AS A SLURRY
3 refills before


Suite 110 Beaverton, OR 97008
LIDOCAINE-ANTACID)
Discrd after 11/24/2022
SLURRY EVERY 6 HOURS
10/20/2023
10/20/2022
FOR BEST SERVICE CALL PHARMACY
BUSINESS DAYS AHEAD FOR REFILLS
PRODUCT IS A PINK SUSPENSION
SHAKE WELL AND REFRIGERATE


Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems


Refrigerators, Freezers and Drug Areas Temperature Monitoring Log
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iOmega>General Operations Manager (Chris)>Cold Drug Storage Systems

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Radiopharmaceuticals

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

[PharmaLogic Salt Lake City, LLC is 100% owned by its parent company, PharmaLogic Holdings Corp, and is not publicly traded nor does it have stockholders.]

Section 1: General Information

Pharmacy Name: PharmaLogic Salt Lake City, LLC

Physical Address: 383 W. Vine Street, Suite 100

City: Salt Lake City State: UT Zip: 84123

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 385-419-4327 Toll Free # (NAC 639.708, NRS 639.23286): 877-769-1433

Fax: 385-425-3132 Contact Email: SaltLakeCityPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new application

Supervising/Managing Pharmacist Name (NRS 639.220): Tyrel Einfeldt

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24064

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Tyrel Einfeldt	NV Pharmacist Registration #: 24064
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): PharmaLogic Holdings Corp

Corporation/Organization Name: PharmaLogic Salt Lake City, LLC

Mailing Address: 383 W. Vine Street, Suite 100

City: Salt Lake City State: Utah Zip: 84123

Telephone: 385-419-4327 Email: SaltLakeCityPharmacy@radiopharmacy.com

Contact Person Name: Tyrel Einfeldt

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: PharmaLogic Holdings Corp

Business Name: PharmaLogic Holdings Corp

Business Address: 5301 N Federal Hwy, Suite 280

City: Boca Raton State: Florida Zip: 33487

Telephone: (561) 416-0085 Email: N/A

Please see attached ownership

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the VP Pharmacy Quality& Regulatory (title) for PharmaLogic Salt Lake City, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jessica Comstock

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

03/14/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Comstock

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

03/14/2024
Date

Board Use Only	Date Received: 4/16/24	Amount: $500-CHECK 200008

Ownership



PharmaLogic Salt Lake City, LLC Officers

Steven Chilinski – President, Treasurer, and Secretary
[redacted]edar Farm Road
Medway, MA 02053
[redacted]
No Medical Professional License
0% Ownership

PharmaLogic Holdings Corp Officers

5301 N Federal Hwy, Suite 280
Boca Raton, FL 33487
All officers listed below have 0% ownership

Steven Chilinski, President & CEO
[redacted]Cedar Farm Rd
Medway, MA 02053
[redacted]
No Medical Professional License

Keith Kennedy, CFO
[redacted]Basingdale Blvd
Vail, CO 81657
[redacted]
No Medical Professional License

Glen Palmer, COO
[redacted]Carr Ave
Clarksburg, WV 26301
[redacted]
Licensed Pharmacist

Scott Holbrook, VP Business Development
[redacted]Boonesboro Rd
Gray, TN 37615
[redacted]
No Medical Professional License

Antonio Romero, VP Sales
[redacted]Mirabella Ct
St. Pete Beach, FL 33706
[redacted]
No Medical Professional License

Anthony Medel, VP Finance
[redacted]Bay Laurel Way
Boca Raton, FL 33487
[redacted]
No Medical Professional License

DocuSign Envelope ID: 0865AEED-1053-405A-A444-280C3ABA428A

JOINT OMNIBUS WRITTEN CONSENT
OF
THE GOVERNING BODIES
(as the case may be) of each of the following entities:

Blue Ridge Isotopes, LLC, a Virginia limited liability company
Clinical Pharmacy Services, Inc., a Tennessee corporation
CPI Pharmacy Services Holding, LLC, a Wisconsin limited liability company
Diagnostic Laboratories, LLC, a Tennessee limited liability company
Hot Shots NM, LLC, an Iowa limited liability company
Hot Shots Nuclear Medicine, LLC, a Wisconsin limited liability company
Invivo Molecular Imaging LLC, a Tennessee limited liability company
Isologic Innovative Radiopharmaceuticals Ltd., a Canadian corporation
PharmaLogic Puerto Rico, Inc., a Puerto Rican corporation
Mid-America Cyclotron, Inc., a Missouri corporation
Mid-America Isotopes, Inc., a Missouri corporation
Nuclear Diagnostics Products Inc., a New Jersey corporation
Nuclear Diagnostics Products of New York Inc., a New York corporation
Nuclear Diagnostics Products of Philadelphia Inc., a New Jersey corporation
PharmaLogic Austin, LLC, a Delaware limited liability company
PharmaLogic Cincinnati, LLC, a Delaware limited liability company
PharmaLogic Colorado, LLC, a Delaware limited liability company
PharmaLogic CSP, Inc., a Delaware corporation
PharmaLogic Optimal Tracers, LLC, a Delaware limited liability company
PharmaLogic Holding Corp., a Delaware corporation
PharmaLogic Ltd., a Vermont corporation
PharmaLogic ME, Inc., a Delaware corporation
PharmaLogic MI, L.L.C., a Michigan limited liability company
PharmaLogic MN, Inc., a Delaware corporation
PharmaLogic Molecular, LLC, a Delaware limited liability company
PharmaLogic MT, Inc., a Delaware corporation
PharmaLogic New York City, LLC, a Delaware limited liability company
PharmaLogic Penn Ltd., a Pennsylvania corporation
PharmaLogic Salt Lake City, LLC, a Delaware limited liability company
PharmaLogic Syracuse, LLC, a New York limited liability company
PharmaLogic WV Ltd., a West Virginia corporation
PharmaLogic WY, Inc., a Delaware corporation
PL Holding, Inc., a Delaware corporation
PL Midco, Inc., a Delaware corporation
PL Topco, LLC, a Delaware limited liability company
Precision Nuclear of Virginia, LLC, a Virginia limited liability company
Precision Nuclear, LLC, a Tennessee limited liability company
Radiopharmacy of Paducah, Inc., a Kentucky corporation
Radiopharmacy, Inc., an Indiana corporation
Rio Grande Valley Isotopes, L.L.C., a Texas limited liability company
UltraSPECT USA, LLC, a Delaware limited liability company
Wisconsin Medical Radiopharmacy, LLC., a Delaware limited liability company
PharmaLogic Salt Lake City, LLC, a Delaware limited liability company
PharmaLogic New York City, LLC, a Delaware limited liability company

June 15, 2022

The undersigned, being (i) the managing member, sole member or sole shareholder (as the case may be), (ii) the managers and (iii) all the members of the board of directors (each, a "**Governing Body**" and together, the "**Governing Bodies**") of the above-named entities (as applicable) (each, a "**Company**" and together, the "**Companies**"), hereby waive notice and consent, pursuant to the applicable statutes and the organizational documents of each such Company, to the adoption of, and do hereby adopt, the following resolutions and agree that said resolutions shall have the same effect as if duly adopted at a meeting of the governing body of such Company held for the purpose:

Board Size Increase

WHEREAS, the authorized number of directors constituting the board of directors or board of managers (as applicable) for each of the Companies managed by a board of directors or board of managers (as applicable) (each a "**Board Managed Company**" and collectively the "**Board Managed Companies**") is currently set at four (4); and

WHEREAS, the Governing Bodies (as applicable) of each Board Managed Company (each, a "**Board**" and collectively, the "**Boards**") have determined that it is in the best interests of the Board Managed Companies (as applicable) to increase the authorized number of directors constituting the board of directors or board of managers (as applicable) from four (4) to five (5).

NOW THEREFORE, BE IT RESOLVED, that the Boards (as applicable) hereby approve the increase in the authorized number of directors constituting the board of directors or board of managers (as applicable) from four (4) to five (5) members.

Appointment of Director

RESOLVED, that the Boards desire to appoint Matthew Beer to serve as a director or manager (as applicable) of the Board Managed Companies, until his successor is duly chosen and qualified or until his earlier death, resignation, removal or disqualification.

RESOLVED FURTHER, that Matthew Beer is hereby elected to the Board of each Board Managed Company, to hold such office until the appointment and qualification of his successor or until his earlier death, resignation, removal or disqualification.

Appointment of Authorized Signatories

RESOLVED, that Jessica Comstock is hereby appointed as an authorized signatory of the Companies (except PL Topco, LLC, a Delaware limited liability company, PL Holding, Inc., a Delaware corporation and PL Midco, Inc., a Delaware corporation (each an "**Authorized Signatory Company**" and collectively the "**Authorized Signatory Companies**")) with respect to matters relating to the completion and submission of pharmacy licenses and no other matters, and that Jessica Comstock be, and hereby is, authorized and empowered from time to time to execute such pharmacy license-related documents and other instruments, in the name and on behalf of the Authorized Signatory Companies, as may be necessary or desirable in order to carry out the day-to-day pharmacy license-related operations of the Authorized Signatory Companies.

RESOLVED, that Ashley Mishoe is hereby appointed as an authorized signatory of each Authorized Signatory Company with respect to matters relating to the completion and submission of regulatory filings and other instruments with the United States Food and Drug Administration ("**FDA**") and no other matters, and that Ashley Mishoe be, and hereby is, authorized and empowered from time to time to execute such FDA-related regulatory filings and other instruments, in the name and on behalf of the Authorized Signatory Companies, as may

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth above.

PHARMALOGIC HOLDINGS CORP., a Delaware corporation,
as Managing Member of the following entities:

Blue Ridge Isotopes, LLC, a Virginia limited liability company
Clinical Pharmacy Services, Inc., a Tennessee corporation
Diagnostic Laboratories, LLC, a Tennessee limited liability company
Hot Shots Nuclear Medicine, LLC, a Wisconsin limited liability company
Isologic Innovative Radiopharmaceuticals Ltd
Mid-America Cyclotron, Inc., a Missouri corporation
Mid-America Isotopes, Inc., a Missouri corporation
Nuclear Diagnostic Products of New York, Inc., a New York corporation
Nuclear Diagnostic Products of Philadelphia Inc., a New Jersey corporation
PharmaLogic Austin, LLC, a Delaware limited liability company
PharmaLogic Cincinnati, LLC, a Delaware limited liability company
PharmaLogic Colorado, LLC, a Delaware limited liability company
PharmaLogic CSP, Inc., a Delaware corporation
PharmaLogic Optimal Tracers, LLC, a Delaware limited liability company
PharmaLogic Ltd., a Vermont corporation
PharmaLogic ME, Inc., a Delaware corporation
PharmaLogic MI, L.L.C., a Michigan limited liability company
PharmaLogic MN, Inc., a Delaware corporation
PharmaLogic Molecular, LLC, a Delaware corporation
PharmaLogic MT, Inc., a Delaware corporation
PharmaLogic New York City, LLC, a Delaware limited liability company
PharmaLogic Optimal Tracers, LLC, a Delaware limited liability company
PharmaLogic Penn Ltd., a Pennsylvania corporation
PharmaLogic Puerto Rico, Inc., a Puerto Rican limited liability company
PharmaLogic Salt Lake City, LLC, a Delaware limited liability company
PharmaLogic Syracuse, LLC, a New York limited liability company
PharmaLogic WV Ltd., a West Virginia corporation
PharmaLogic WY, Inc., a Delaware corporation
Precision Nuclear of Virginia, LLC, a Virginia limited liability company
Precision Nuclear, LLC, a Tennessee limited liability company
Radiopbarmacy of Paducah, Inc., a Kentucky corporation
Radiopharmacy, Inc., an Indiana corporation
Rio Grande Valley Isotopes, L.L.C., a Texas limited liability company
UltraSPECT USA, LLC, a Delaware limited liability company
Wisconsin Medical Radiopharmacy, LLC., a Delaware limited liability company

By: _____
Name: Steven Chilinski
Title: President

be necessary or desirable in order to carry out FDA-related regulatory filings and other instruments for the Authorized Signatory Companies.

General

RESOLVED, to authorize, empower and direct the Authorized Officers, as applicable, and each of them acting singly (i) to execute, enseal and deliver in the name of and on behalf of the applicable Company any and all documents, agreements and instruments to effectuate any of the foregoing resolutions, all with such changes therein as any of such Authorized Officers may deem necessary or desirable, and (ii) to take such action (including without limitation the filing of any and all applications and the payment of any and all filing fees and expenses), or to cause the applicable Company or any other person to take such action as may in the judgment of such Authorized Officer so acting be necessary or desirable in connection with, or in furtherance of, any of the foregoing resolutions, and the execution and delivery of any such document, agreement or instrument or the taking of any such action shall be conclusive evidence of such Authorized Officer's authority hereunder to so act.

RESOLVED FURTHER, to ratify, confirm and approve all actions taken by the directors and/or the officers of each Company, as applicable, in connection with any and all of the transactions referred to in or contemplated by any of the foregoing resolutions.

RESOLVED FURTHER, that this consent may be signed in multiple counterparts, including by facsimile or other electronic transmission, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same instrument.

RESOLVED FURTHER, to direct that this consent be filed with the records of the applicable Governing Body.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth above.

MANAGING MEMBERS (cont.):

HOT SHOTS NUCLEAR MEDICINE, LLC, a Wisconsin limited liability company,
as Managing Member of the following entities:

Hot Shots NM, LLC, an Iowa limited liability company
CPI Pharmacy Services Holding, LLC, a Wisconsin limited liability company

By: PharmaLogic Holdings, Corp.
Its: Managing Member

By: Steve Chilinski
Name: Steven Chilinski
Title: President

**DIAGNOSTIC LABORATORIES, LLC, a Tennessee limited liability company,
as Managing Member of Invivo Molecular Imaging LLC, a Tennessee limited liability company**

By: PharmaLogic Holdings, Corp.
Its: Managing Member

By: Steve Chilinski
Name: Steven Chilinski
Title: President

DocuSign Envelope ID: 0865AEED-1053-405A-A444-280C3ABA428A

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

THE BOARDS AND MANAGERS (as applicable) of the following entities:

Clinical Pharmacy Services, Inc., a Tennessee corporation
Mid-America Cyclotron, Inc., a Missouri corporation
Mid-America Isotopes, Inc., a Missouri corporation
PharmaLogic CSP, Inc., a Delaware corporation
PharmaLogic Ltd., a Vermont corporation
PharmaLogic ME, Inc., a Delaware corporation
PharmaLogic MI, L.L.C., a Michigan limited liability company
PharmaLogic MN, Inc., a Delaware corporation
PharmaLogic MT, Inc., a Delaware corporation
PharmaLogic Penn Ltd., a Pennsylvania corporation
PharmaLogic WV Ltd., a West Virginia corporation
PharmaLogic WY, Inc., a Delaware corporation
PL Topco, LLC, a Delaware limited liability company
Radiopharmacy of Paducah, Inc., a Kentucky corporation

Steve Chilinski — Date: 06/15/22

John Garbarino — Date: 06/15/22

David Malm — Date: 06/15/22

Brandon Ingersoll — Date: 06/15/22

DocuSign Envelope ID: 0865AEED-1053-405A-A444-280C3ABA428A

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of Radiopharmacy, Inc., an Indiana corporation

DocuSigned by:
Steve Chilinski

Steve Chilinski

06/15/22
Date:

DocuSigned by:
David Malm

David Malm

06/15/22
Date:

DocuSigned by:
Brandon Ingersoll

Brandon Ingersoll

06/15/22
Date:

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of Isologic Innovative Radiopharmaceuticals Ltd., a Canadian corporation

Andre Gagnon — Date: 06/15/22

David Malm — Date: 06/15/22

Brandon Ingersoll — Date: 06/15/22

John Garbarino — Date: 06/15/22

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of Nuclear Diagnostics Products Inc., a New Jersey corporation Nuclear Diagnostics Products of New York Inc., a New York corporation, and Nuclear Diagnostics Products of Philadelphia Inc., a New Jersey corporation

David Malm — Date: 06/15/22

Steve Chilinski — Date: 06/15/22

Brandon Ingersoll — Date: 06/15/22

John Garbarino — Date: 06/15/22

DocuSign Envelope ID: 0865AEED-1053-405A-A444-280C3ABA428A

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of PharmaLogic Puerto Rico, Inc., a Puerto Rican corporation

David Malm — 06/15/22
David Malm — Date

Steve Chilinski — 06/15/22
Steve Chilinski — Date

Brandon Ingersoll — 06/15/22
Brandon Ingersoll — Date

John Garbarino — 06/15/22
John Garbarino — Date

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of PL Midco, Inc., a Delaware corporation

David Malm — 06/15/22
David Malm — Date

Steve Chilinski — 06/15/22
Steve Chilinski — Date

Brandon Ingersoll — 06/15/22
Brandon Ingersoll — Date

John Garbarino — 06/15/22
John Garbarino — Date

WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of PL Topco, LLC, a Delaware limited liability company

David Malm — Date: 06/15/22

Steve Chilinski — Date: 06/15/22

Brandon Ingersoll — Date: 06/15/22

John Garbarino — Date: 06/15/22

DocuSign Envelope ID: 0865AEED-1053-405A-A444-280C3ABA428A

WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of PL Holding, Inc, a Delaware corporation

David Malm — 06/15/22
David Malm — Date

Steve Chilinski — 06/15/22
Steve Chilinski — Date

Brandon Ingersoll — 06/15/22
Brandon Ingersoll — Date

John Garbarino — 06/15/22
John Garbarino — Date

State Of Delaware

Entity Details

4/12/2024 8:12:14AM

File Number: 4446038
Incorporation Date / Formation Date: 12/15/2020
Entity Name: PHARMALOGIC SALT LAKE CITY, LLC
Entity Kind: Limited Liability Company
Entity Type: General
Residency: Domestic
State: DELAWARE
Status: Good Standing
Status Date: 12/15/2020

Registered Agent Information

Name: REGISTERED AGENT SOLUTIONS, INC.
Address: 838 WALKER ROAD SUITE 21-2
City: DOVER
Country:
State: DE
Postal Code: 19904
Phone: 888-716-7274

State Of Delaware

Entity Details

4/12/2024 8:12:14AM

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City: DOVER
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Phone: 888-716-7274

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741

Phone: (801) 530-6628
Toll Free: (866) 275-3675
Online: DOPL.utah.gov
Email: DOPLInvestigations@utah.gov

CLASS B
CLOSED DOOR

INSPECTION

☑ Opening ☐ Random

INFORMATION

Pharmacy Name: PharmaLogic Salt Lake City, LLC Date: 12/11/23

License Number: 13665759-1704 Exp Date: 9/30/25

C.S. License Number: n/a Exp Date:

DEA Registration: n/a Exp Date:

Pharmacy FEIN # (Tax ID): 86-1181199

Pharmacy Email: teinfeldt@radiopharmacy.com

Pharmacy Phone: 385-419-4327 Fax: 385-425-3132

Toll Free Number: 877-769-1433

Affiliated Websites: radiopharmacy.com

Pharmacy Hours: Monday-Friday: 8:00-4:00 Saturday: Closed Sunday: Closed

Pharmacy Address: 383 W Vine St Ste 100

City: Salt Lake City State: UT Zip: 84123

Pharmacist In Charge (PIC): Tyrel Rick Einfeldt

PIC License # 7053291-1701 Expiration Date: 9/30/25

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

CLASS B CLOSED DOOR INSPECTION

Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

INSPECTION

	YES	NO	
1	☑	☐	Class B pharmacy means a pharmacy located in Utah that is authorized to provide pharmaceutical care for patients in an institutional setting; and whose primary purpose is to provide a physical environment for patients to obtain health care services; and includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and pharmaceutical administration and sterile product preparation facilities. [UCA 58-17b-102 (11)(a)(i-ii)(b)(i-ii)]
2	☐	☑	The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-iv)(b)]
3	☑	☐	Notification has been provided to the Division in regards to the unique email address used in self audits or alerts for the pharmacy. The pharmacy will notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603(3)(t) (i-ii)]
4	☑	☐	Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
5	☐	☐	If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ☑ N/A
6	☑	☐	A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist or two pharmacy technician trainees to one pharmacist, if a licensed pharmacy technician or intern is working during the same shift [UAC R156-17b-601(4)(a)(i-ii)]
7	☑	☐	Pharmacy technicians shall have general supervision by a pharmacist. [UCA 58-17b-102 (57)]
8	☑	☐	The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(3)(a)]
9	☑	☐	In accordance with Subsecton 58-17b-102(72)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)]
10	☑	☐	In accordance with Subsection 58-17b-102(72)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including: stock ordering and restocking; cashiering; billing; filing; receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP desigenee; housekeeping; and delivering a pre-filled prescription to a patient. [UAC R156-17b-607 (1)(a-g)]

11 ☑ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

12 ☑ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

13 ☑ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

14 ☑ ☐ The facility or parent company does maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

15 ☑ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]

- ☑ UCA 58-1 (DOPL Licensing Act)
- ☑ UAC R156-1 (General Rules of DOPL)
- ☑ UCA 58-17b (Pharmacy Practice Act)
- ☑ UAC R156-17b(Pharmacy Practice Act Rules)
- ☑ UCA 58-37 (Controlled Substance Act)
- ☑ UAC R156-37(Controlled Substance Act Rules)
- ☑ UCA 58-37f (Controlled Substance Database Act)
- ☑ UAC R156-37f (Controlled Substance Database Act Rule)
- ☑ Code of Federal Regulations Title 21 parts 1300 to end
- ☑ FDA Approved Drug Product(Orange Book)
- ☑ General Drug References

16 ☑ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

17 ☑ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1) (b)(c)]

18 ☑ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1)(d)(ii)(ii)]

19 ☑ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]

20 ☑ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605 (1)]

21 ☑ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (f)]

22 ☐ ☐ n/a If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1)(g)(i-ii)(h)(i-ii)]

23 ☑ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] ☐ N/A

24 ☑ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]

25 ☑ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156-17b-614a(6)]

26 ☑ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)]

27 ☑ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log entry for three years. [UAC R156-17b-614a (3)]

28 ☑ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☑ Inappropriate drug utilization
- ☑ Therapeutic duplications
- ☑ Drug-disease contraindications
- ☑ Drug-drug interactions
- ☑ Incorrect drug dosage
- ☑ Incorrect duration of drug treatment
- ☑ Drug-allergy interactions
- ☑ Clinical abuse or misuse

29 ☑ ☐ Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs. [R156-17b-610 (7)]

30 ☐ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

n/a

31 ☐ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

n/a

32 ☐ ☐ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

n/a

☐ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing:
(a) the name and description of the prescription drug;
(b) the dosage form, dose, route of administration and duration of drug therapy;
(c) intended use of the drug, when known, and expected action;
(d) special directions and precautions for preparation, administration and use by the patient;
(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered,
including their avoidance, and the action required if they occur;
(f) techniques for self-monitoring drug therapy;
(g) proper storage;
(h) prescription refill information;
(i) action to be taken in the event of a missed dose;
(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or
drug; and
(k) the date after which the prescription should not be taken or used, or the beyond use date.

☐ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

☐ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information

n/a **33** ☐ ☐ Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication [UAC R156-17b-610(1)]

n/a **34** ☐ ☐ A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses counseling. [UAC R156-17b-610(2)]

n/a **35** ☐ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

36 ☑ ☐ A pharmacy may only deliver a prescription drug to a patient or a patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or return to the pharmacy. [UCA 58-17b-602 (9)(a)(b)(i-ii)]

n/a **37** ☐ ☐ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee: [UAC R156-17b-608(1)(a-e)(2)(a-c)]

☐ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☐ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☐ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☐ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counseling.

☐ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment.

38 ☑ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]

- ☑ name, address, & phone number of pharmacy
- ☑ filling date or last dispensing date
- ☑ name of the prescriber
- ☑ trade, generic or chemical name
- *(Unless Otherwise Indicated by Prescriber)*
- ☑ serial number of prescription
- ☑ name of the patient or animal owner/species
- ☑ directions for use & cautionary statements
- ☑ amount dispensed & strength of dosage form
- ☑ beyond use date

39 ☑ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [UAC 58-1-502(6)& 16 CFR 1700.14]

40 ☑ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

41 ☑ ☐ The registered pharmacy does only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [UAC R156-17b-613(1) & CFR, Title 21, Chapter 11, Section 1311]

42 ☑ ☐ Prescription files, including refill information, are maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

43 ☑ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders.
[UAC R156-37-602 (4) (a-b)]

44 ☐ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
n/a [UAC R156-37-602(3) (5)]

45 ☐ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
n/a [UAC R156-37-602(3) (6)]

n/a **46** ☐ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

n/a **47** ☐ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection(4) of this section. [UAC R156-17b-605 (3)(a-c)]

☐ N/A

n/a **48** ☐ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605(2)(a)(b)(c)(f)(g)(h)(k)(l)]

☐ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

☐ the inventory records shall be maintained for a period of five years and be readily available for inspection

☐ the inventory shall be filed separately from all records

☐ the inventory may be taken either as the opening of the business or the close of business on the inventory date;

☐ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☐ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

☐ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

n/a **49** ☐ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(6)]

n/a **50** ☐ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

n/a **51** ☐ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

n/a **52** ☐ ☐ Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]

n/a **53** ☐ ☐ The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]

n/a **54** ☐ ☐ The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a (9)(a-c)]

55	☑	☐	The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]
56	☑	☐	In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, identification number used, and first and last name of the individual picking up dispensed drug. [UCA R156-37f-203 (4) (bb-ff)]
57	☐	☑	The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.
58	☐	☑	The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.
59	☐	☑	The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]
60	☐	☑	Does the pharmacy purchase any compound products from other entities for dispensing to patients? [UAC 58-17b-102(18)(b)(i)]
61	☐	☑	The facility is engaged in compounding with hazardous drugs as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.
62	☐	☑	The facility is engaged in simple, medium, or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (2)]
63	☑	☐	The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (2)]

COMMENTS

Assisted by Tyrel Einfeldt.

Pharmacy needs a list of licensed pharmacy employees.

Nuclear pharmacy that will be serving IHC hospitals.

No controlled substances or Controlled Substance license.

Utah Radioactive Materials License # UT1800645. Expires on 07/31/2028.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: [signature] Date: 12/11/23

Name of Responsible Party (Print): Tyrel Einfeldt

Signature of Division Investigator: [signature] Date: 12/11/23

Name of Division Investigator (Print): Travis Drebing

Revised 8/2023

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

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STERILE COMPOUNDING

INSPECTION

☑ Opening ☐ Random

INFORMATION

Pharmacy Name: PharmaLogic Salt Lake City, LLC Date: 12/11/23

Pharmacy License Number: 13665759-1704 Expiration Date: 9/30/25

Controlled Substance License Number: n/a Expiration Date:

DEA Registration Number: n/a Expiration Date:

Pharmacist-in-Charge (PIC): Tyrel Rick Einfeldt

Pharmacist-in-Charge License Number: 7053291-1701 Expiration Date: 9/30/25

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:(a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations [UAC R156-17b-614a (3)]

	Yes	No	**GENERAL OPERATIONS AND INFORMATION**
			Which categories of compounding does the facility perform?
1.	☑	☐	The pharmacy does perform compounding identified as **low-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Low-Risk Level CSPs]* ☑ The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices. ☑ The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/ device to prepare the CSP. ☑ Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing. ☑ For a low-risk level preparation, in the absence of passing a sterility teste (see Sterility Tests <71>) the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25°and -10°.
	☐	☑	The pharmacy does perform compounding identified as **medium-risk**. When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exist, such CSPs are at a medium risk of contamination. [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Medium-Risk Levels CSPs]* ☐ Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to either multiple patients or to one patient on multiple occasions. ☐ The compounding process includes complex aseptic manipulations other than the single-volume transfer. ☐ The compounding process requires unusually long duration, such as that required to compete dissolution or homogenous mixing. ☐ For a medium-risk preparation, in the absence of passing a sterility test (see Sterility Tests <71>0, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see Generals Notices and Requirements), and for 45 days in solid frozen state between 25°and -10°.

☐ ☑ The pharmacy does perform compounding identified as **high-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- High-Risk Levels CSPs]*
☐ Non sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g. oral), are incorporated or a non-sterile device is employed before terminal sterilization.
☐ Any of the following are exposed to air quality worse than ISO 5 for more than 1 hour (see *Immediate-Use CSPs*):
☐ Sterile contents of commercially manufactured products,
☐ CSPs that lack effective antimicrobial preservative, and
☐ Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs

☐ Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment).*
☐ Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.
☐ It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection under Pharmaceutical Compounding- Non-Sterile Preparations <795>).*
☐ In the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements),* for not more than 3 days at a cold temperature (*see General Notices and Requirements),* and for 45 days in a solid frozen state between 25°and -10°.

☑ ☐ **Immediate-use provision in intended only for those situation where there is a need for emergency or immediate patient administration of a CSP.** Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs. [USP-NF Chapter 797- *Immediate-use CSPs*]

☑ ☐ **Immediate-use CSPs** are exempt from the requirements described for Low-Risk Label CSPs only when all of the following are met: [USP-NF Chapter 797- *Immediate-use CSPs]*
☐ The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturer's' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
☐ Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
☐ During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mixups with other CSPs, and direct contact of outside surfaces.
☐ Administration begins not later than 1 hour following the start of the preparation of the CSP.
☐ Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
☐ If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

2. ☑ ☐ Does the facility dispense sterile compounded preparations pursuant to a prescription?

3. ☑ ☐ Does the facility make sterile compounded preparations that are delivered to a practitioner for administration to a patient in an office, clinic, or facility?

4. ☐ ☑ A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical

Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]

5. ☑ ☐ Does the facility distribute sterile compounded preparations to hospitals, clinics, or surgery centers?

6. ☐ ☑ Does the facility have a sales force that distributes samples containing active ingredients? If so, list samples on separate sheet.

7. ☐ ☑ Does the facility compound sterile preparations for veterinary use?

8. ☐ ☑ Is the facility registered with the FDA as an "Outsourcing Facility"?

9. ☑ ☐ The facility does compound:

☐ allergen extracts	☐ baths and soaks for live organs and tissues
☑ parental solutions	oral or nasal inhalation preparations
☐ parenteral suspensions	irrigations for wounds and body cavities
☐ preservative-free parenterals	ophthalmic preparations

10. ☐ ☑ Does the facility compound investigational drugs? If so, list on separate sheet.

11. ☑ ☐ The facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UAC 58-17b-102(18)(b)(ii)]

12. ☑ ☐ The facility does not prepare a prescription drug for sale to another pharmacist or pharmaceutical facility. [UAC 58-17b-102 (18)(b)(i)]

13. ☑ ☐ The facility does not prepare a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons. [UAC 58-17b-102 (18)(b)(iii)

14. ☐ ☑ Does the pharmacy makes sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients?

15. ☐ ☑ Bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness. [UAC R156-17b-614a (3)(c)(i)(ii)]

16. ☐ ☑ Does the facility have a lyophilizer?

17. ☐ ☐ **The compounding facility shall have written, properly approved SOPs** designed to ensure the quality of the environment in which a CSP is prepared. [USP-NF Chapter 797-*Responsibility of Compounding Personnel-Suggested Standard Operating Procedures (SOPs)]*

a. ☑ Procedures for **measuring, mixing, dilution, purification, sterilization, packaging, and labeling** conform to the correct sequence and quality established for the specified CSP. [USP-NF Chapter 797- *Responsibility of Compounding Personnel*]

b. ☑ All **cleaning and disinfecting** practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control and Disinfecting the Compounding Area*]

- ☑ ISO Class 5 PEC (e.g. LAFW, BSC, CAI, CACI)
- ☑ Counters and easily cleanable work surfaces
- ☑ Floors
- ☑ Walls
- ☑ Ceiling
- ☑ Storage Shelving

c. ☑ It is necessary that **equipment, apparatus, and devices** used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. [USP-NF Chapter 797- *Element of Quality Control, Equipment]*

- ☑ Equipment calibration
- ☑ Annual maintenance
- ☑ Monitoring for proper function and controlled procedures for use of the equipment and specified time frames for these activities
- ☑ Routine maintenance and frequencies

d. ☑ The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for **maintaining and working within the PEC** area shall be written and followed. The policies and procedure will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Control]*

e. ☐ When compounding activities require **the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling** procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross contamination. [USP-NF Chapter 797- *Environmental Quality and Control- Additional Personnel Requirements*] n/a

f. ☑ **Double-checking compounding** accuracy shall be followed for every CSP during preparation and immediately prior to release. [USP-NF Chapter 797- *Preparation Release Checks and Tests, Compounding Accuracy Checks*]

g. ☐ When **high-risk level CSPs are dispensed before receiving the results of their sterility tests**, there shall be a written procedure requiring daily observations of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Sterility Testing*] n/a

h. ☑ **Verifying the correct identity and quality** of CSPs before they are dispensed and administered: [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Identify and Strength Verification of Ingredients*]

- ☑ Labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
- ☑ That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
- ☑ That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

i. ☑ To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the **determination of the BUDs** for all compounded products. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions. [USP-NF Chapter 797- *Storage and Beyond-Use Dating*]

j. ☑ The **compounding procedures and sterilization methods** for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Stability*]

k. ☑ Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for **unit-by-unit physical inspection preparatory to use** is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use. [USP-NF Chapter 797- *Elements of Quality Control- Ingredients and Devices- Sterile Ingredients and Devices*]

l. ☑ Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper **packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions**. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks involving any of these responsibilities, the policies and procedures encompassing those tasks should be developed by compounding supervisors. [USP-NF Chapter 797- Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs]

m. ☑ Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as **transport, handling, and placement into storage, may be fulfilled by noncompounding personnel** who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures. [USP- NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packaging, Handling, and Transport*]

n. ☑ **When CSPs are distributed to locations outside the premises** in which they are compounded, compounding personnel select packing containers and materials that are **expected to maintain physical integrity, sterility, and stability of CSPs during transit.** Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Packing CSPs for Transit*]

o. ☑ SOPs must exist to ensure that **storage conditions in the patient-care setting** are suitable for the CSP-specific storage requirements. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs, Use and Storage*]

- ☑ Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8°
- ☑ and the monthly inspection of all drug storage locations by compounding personnel.

p. ☑ The SOP manuals of compounding facilities shall describe **specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation** claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP. [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

Personnel Training and Requirements

18. ☑ ☐ A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. **Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs** (see Personnel Training and Evaluation in Aseptic Manipulation Skills and Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures). [USP-NF Chapter 797 - *Elements of Quality Control*]

19. ☑ ☐ **Personnel who prepare CSPs shall be trained** conscientiously and skillfully **by expert personnel, multi-media instructional sources, and professional publications** in the theoretical principles and practical skills of **garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.** [USP-NF Chapter 797- *Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

20. ☑ ☐ Compounding personnel shall complete: [USP-NF Chapter 797- *Appendices- Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

- ☑ didactic training,
- ☑ undergo skill assessment using observational audit tools,
- ☑ pass written competence assessments,
- ☑ and media-fill testing.

21. ☑ ☐ **Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures** (see *Personnel Cleansing* and *Garbing* under *Personnel Training and Evaluation in Aseptic Manipulation Skills* above). **The visual observation shall be documented** on a form such as the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel (see Appendix III) and maintained to provide a permanent record and long-term assessment of personnel competency. [USP-NF Chapter

797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

22. ☑ ☐ **Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding** because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling **shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs.** All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

23. ☑ ☐ **Sterile contact agar plates shall be used to sample the gloved fingertips** of compounding personnel **after garbing** in order to assess garbing competency and **after completing the media-fill preparation** (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

24. ☑ ☐ **All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use.** Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see Incubation Period). **After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs** using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

25. ☑ ☐ **After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.** Records of these evaluations will be maintained using a form such as the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel (see Appendix IV) and maintained to provide a permanent record of and long-term assessment of personnel competency. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

26. ☑ ☐ **Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding.** Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies. [USP-NF Chapter 797- *Personnel Training and Evaluation in Aseptic Manipulation Skills*]

27. ☑ ☐ **Compounding personnel and other personnel responsible for cleaning shall he visually observed during** the process of performing **cleaning and disinfecting procedures**, during **initial personnel training** on cleaning procedures, during **changes in cleaning staff**, and at the **completion of any media-fill test procedure** (see Cleaning and Disinfecting of Compounding Areas). [USP-NF Chapter 797- Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/ Disinfection-Procedures, Surface Cleaning and Disinfection Sampling and Assessment]

28. ☑ ☐ **In the event that cleaning and disinfecting procedures are also performed by other support personnel** (e.g., institutional environmental services, housekeeping), thorough training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support **personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures*]

29. ☐ ☐ **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The **training shall include** at least the following: [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]

n/a
- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

Handwashing and Garbing

30. ☑ ☐ **When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates.** Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. **Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

31. ☑ ☐ **Before entering the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), **compounding personnel shall remove personal outer garments** (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); **all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings** (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). **The wearing of artificial nails or extenders is prohibited** while working in the sterile compounding environment. **Natural nails shall be kept neat and trimmed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

32. ☑ ☐ **Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.** Garbing activities considered the dirtiest include donning of ☑ dedicated shoes or shoe covers, ☑ head and facial hair covers (e.g., beard covers in addition to face masks), and ☑ face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

33. ☑ ☐ **After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area.** The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lintfree disposable towels or an electronic hand dryer. ☑ **After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned.** Gowns designated for buffer area use shall be worn, and **preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

34. ☐ ☐ **Once inside the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), and **prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves. [USP-NF Chapter 797- Environmental Quality and Control - Personnel Cleansing and Garbing]**

35. ☑ ☐ **Sterile gloves shall be the last item donned before compounding begins.** Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. **Routine application of sterile 70% IPA shall occur throughout the compounding process** and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched. **Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.** Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

36. ☑ ☐ **When compounding personnel exit the compounding area** during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, **shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

37. ☐ ☐ n/a **During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5** (see Table 1) environment. Properly garbed and gloved **compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see Table 1) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon reentering the ISO Class 7 (see Table 1) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see Table 1) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

38. ☑ ☐ **Cleaning and disinfecting shall occur before compounding is performed.** Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water soluble solid residues are removed with sterile water (for injection or irrigation) and lowshedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

39. ☑ ☐ **Cleaning Requirements**

Cleaning and disinfecting surfaces in the **LAFWs, BSCs, CAIs, and CACIs** are the most critical practices before the preparation of CSPs. Consequently, such **surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

40. ☑ ☐ **Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily**, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality (see Disinfectants and Antiseptics <1072>). [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

41. ☑ ☐ **Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress.** Mopping shall be performed by trained personnel using approved agents and procedures described in the

written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

42. ☑ ☐ In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

43. ☑ ☐ **Cleaning and disinfecting agents** are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see Appendix II). Their **schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

44. ☑ ☐ All **cleaning materials, such as wipers, sponges, and mops, shall be nonshedding**, preferably composed of synthetic micro fibers, and **dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.** Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

45. ☑ ☐ **Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent** (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant **shall be allowed to dry, during which time the item shall not be used for compounding purposes.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

Facilities and Environmental Monitoring

46. ☑ ☐ Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. **Surface sampling shall be performed in all ISO classified areas on a periodic basis.** Sampling can be accomplished using contact plates or swabs, and it **shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form.** The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Surface Cleaning and Disinfection Sampling and Assessment*]

47. ☑ ☐ The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. **Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797- *Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation*]

48. ☑ ☐ Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. [USP-NF Chapter 797- Environmental Quality and Control- Additional Personnel Requirements]

49. ☑ ☐ **Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups** among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see Pharmaceutical Compounding—Sterile Preparations <797>, Environmental Quality and Control). [USP-NF Chapter 795- Compounding Facilities]

50. ☑ ☐ The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls]*

51. ☑ ☐ Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

52. ☑ ☐ Any other penetrations through the ceiling or walls shall be sealed. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

53. ☑ ☐ The buffer area shall not contain sources of water (sinks) or floor drains. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

54. ☑ ☐ Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

55. ☑ ☐ Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

56. ☑ ☐ There shall be some demarcation designation that separates the ante-area from the buffer area. [USP-NF Chapter 797-Environmental Quality and Control- Additional Personnel Requirements]

57. ☑ ☐ **To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility.** Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, –25° and –10° (see General Notices and Requirements) if needed to achieve freezing, and the media-specific temperature range for microbial culture media. **A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations.** Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. **If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.** [USP-NF Chapter 797- *Storage and Beyond Use Dating- Monitoring Controlled Storage Areas*]

58. ☑ ☐ **Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered.** Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following: [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Total Particle Counts*]

- ☑ ISO Class 5: not more than 3520 particles 0.5 mm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;
- ☑ ISO Class 7: not more than 352,000 particles of 0.5 mm size and larger per cubic meter of air for any buffer area;
- ☑ ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area.

59. ☑ ☐ **All certification records shall be maintained and reviewed by supervising personnel or other designated employees** to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Total Particle Counts*]

60. ☑ ☐ A **pressure gauge or velocity meter shall be installed to monitor the pressure** differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitaring*]

61. ☑ ☐ **The results shall be reviewed and documented on a log at least every work shift** (minimum frequency shall be at least daily) or by a continuous recording device. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

62. ☑ ☐ **The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.** [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

63. ☑ ☐ **The buffer area shall maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm and larger particles under dynamic operating conditions.** The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

64. ☑ ☐ For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05- inch water column is required. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

65. ☑ ☐ For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

66. ☑ ☐ **An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30.** The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

67. ☑ ☐ **HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall,** creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

68. ☑ ☐ **Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.** Only the **furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.** Whenever such items are **brought into the area, they shall first be cleaned and disinfected.** Whenever possible, **equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.** [USP-NF Chapter 797- Environmental Quality and Control- Facility Design and Environmental Controls]

69. ☑ ☐ Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. **Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas.** [USP-NF Chapter 797 *Environmental Quality and Control, Facility Design and Environmental Controls*]

70. ☑ ☐ **PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas)** are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. **Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Nonviable Particle Testing Program*]

71. ☑ ☐ PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see Table 1) environment for the exposure of critical sites. **PECs shall maintain ISO Class 5 (see Table 1) or better conditions for 0.5-mm particles (dynamic operating conditions) while compounding CSPs.** [USP-NF Chapter 797 -*Environmental Quality and Control, Facility Design and Environmental Controls*]

72. ☑ ☐ **The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.** For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

73. ☑ ☐ **PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1),** with the following CAI/CACI exceptions below: [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
☑ Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
☑ Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment.
☑ PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

74. ☐ ☐ **CAIs and CACIs shall be placed in an ISO Class 7 (see Table 1) buffer area unless they meet all of the following conditions:** [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
n/a
☐ The isolator shall provide isolation from the room and maintain ISO Class 5 (see Table 1) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
☐ Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see Table 1) levels during compounding operations.
☐ Not more than 3520 particles (0.5 mm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.

75. ☐ ☐ **If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see Table 1) buffer area,** then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
n/a

76. ☐ ☐ When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. [USP-NF Chapter 797 - Environmental Quality and Control, Facility Design and Environmental Controls]
n/a

77. ☐ ☐ n/a

Airborne contamination control is achieved in the PEC through the use of HEPA filters. **The airflow in the PEC shall be unidirectional (laminar flow),** and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, **free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see Table 1) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations.** Proper design and control prevents turbulence and stagnant air in the critical area. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

78. ☑ ☐

In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

79. ☑ ☐

Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions: [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing*]

☑ as part of the commissioning and certification of new facilities and equipment;
☑ following any servicing of facilities and equipment;
☑ as part of the re-certification of facilities and equipment (i.e., every 6 months);
☑ in response to identified problems with end products or staff technique; or
☑ in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

80. ☑ ☐

Sampling Plan—**An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 (see Table 1) environment and in the ISO Class 7 and 8 (see Table 1) areas and in the segregated compounding areas at greatest risk of contamination** (e.g., work areas near the ISO Class 5 [see Table 1] environment, counters near doors, pass-through boxes). **The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

81. ☑ ☐

Growth Medium—**A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in highrisk level compounding environments.** Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

82. ☑ ☐

Viable Air Sampling—**Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments** (LAFWs, CAIs, clean room or buffer areas, and ante-areas) **shall be performed by properly trained individuals for all compounding risk levels. Impaction shall he the preferred method of volumetric air sampling.** Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

83. ☑ ☐

For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see Table 1] PEC and environments). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

84. ☑ ☐

For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) **that maintains an**

ISO Class 5 (see Table 1), **air sampling shall be performed at locations inside the ISO Class 5** (see Table 1) **environment and other areas that are in close proximity to the ISO Class 5** (see Table 1) **environment during the certification of the PEC.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

85. ☑ ☐ Air Sampling Devices—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. **A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

86. ☑ ☐ Air Sampling Frequency and Process—**Air sampling shall be performed at least semiannnally (i.e., every 6 months) as part of the re-certification of facilities and equipment.** If compounding occurs in multiple locations within an institution (e.g., main pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

87. ☑ ☐ Action Levels, Documentation, and Data Evaluation—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. **Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

88. ☑ ☐ **Any cfu count that exceeds its respective action level (see Table 2) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted.** Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. **The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

89. ☑ ☐ The intermediate precision of the **ACD** can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, **compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time.** [USP-NF Chapter 797 - *Elements of Quality Control- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding- Precision*]

90. ☑ ☐ **Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients.** In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs*]

91. ☑ ☐ CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Use and Storage*]

Documentation

All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section. [UAC R 156-17b-614a (3)(d)]

92. ☐ ☐ n/a

A master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet may be stored electronically and shall contain at a minimum: [UAC R156-17b-614a(3)(e)(i-xiii)]

☐ official or assigned name
☐ strength
☐ dosage form of the preparation
☐ calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients dosage form of the preparation
☐ description of ingredients and their quantities
☐ compatibility and stability information, including references when available
☐ equipment needed to prepare the preparation
☐ container used in dispensing
☐ packaging and storage requirements
☐ description of final preparation
☐ quality control procedures and expected results;
☐ mixing instructions, which shall include: ☐order of mixing ☐ mixing temperatures or other environmental controls ☐ duration of mixing ☐ other factors pertinent to the replication of the preparation as compounded
☐ sample labeling information, which shall contain, in addition to legally required information: ☐ generic name and quantity or concentration of each active ingredient ☐ assigned beyond use date ☐ storage conditions ☐ prescription or control number, whichever is applicable

93. ☐ ☐ n/a

A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following: [UAC R156-17b-614a(3)(f) (i-xix)]

☐ official or assigned name;
☐ strength and dosage of the preparation;
☐ Master Formulation Record reference for the preparation;
☐ names and quantities of all components
☐ sources, lot numbers, and expiration dates of components;
☐ total quantity compounded;
☐ name of the person who prepared the preparation
☐ name of the compounder who approved the preparation
☐ name of the person who performed the quality control procedures
☐ date of preparation
☐ assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable
☐ duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain: ☐ active ingredients ☐ beyond use date ☐ storage conditions and ☐ lot number;
☐ proof of the duplicate labeling information, which proof shall: ☐ be kept at the pharmacy ☐ be immediately retrievable ☐ include an audit trail for any altered form; and ☐ be reproduced in: the original format that was dispensed, an electronic format, or a scanned electronic version
☐ description of final preparation
☐ results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
☐ documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

94. ☑ ☐ Compounding records including the master worksheet, preparation worksheet, and MSDS files shall be kept for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

95. ☑ ☐ The facility maintains documentation regarding an ongoing quality control program that monitors and evaluates personnel performance, equipment and facility's compliance with following the USP-NF Chapters 795 and 797 standards. [UAC R156-17b-614a(3)(h)]

96. ☑ ☐ Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. [USP-NF Chapter 797- *Elements of Quality Control- Equipment*]

Compounding Procedures

97. ☑ ☐ **Opened or needle-punctured single-dose containers,** such as bags, bottles, syringes, and vials of sterile products and CSPs **shall be used within 1 hour if opened in worse than ISO Class 5** (see Table 1) air quality (see Immediate-Use CSPs), **and any remaining contents must be discarded.** [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

98. ☑ ☐ ☑**Single-dose vials exposed to ISO Class 5** (see Table 1) **or cleaner air may be used up to 6 hours after initial needle puncture.** ☑**Opened single-dose ampuls shall not be stored for any time period.** ☑**Multiple-dose containers** (e.g., vials) **are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.** The ☑**BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days** (see Antimicrobial Effectiveness Testing <51>) unless otherwise specified by the manufacturer. [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

99. ☑ ☐ Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. **The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

100. ☑ ☐ Pharmacy Bulk Package (see Containers for Injections under Injections <1>)—A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. **The closure shall be penetrated ouly one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents.** The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). **Where a container is offered as a pharmacy bulk package, the label sball (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has heen entered, provided it is held under the labeled storage conditions.** [USP-NF Chapter 797- *Definitions*]

101. ☑ ☐ **The licensed healthcare professionals who snpervise compounding shall be responsihle for determining that the selected sterilization method** (see Methods of Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility, Sterilization Methods*]

102. ☑ ☐ Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. [USP-NF Chapter 797 - Exposure of Critical Sites]

103. ☐ ☐ **All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages** (e.g., ampuls, bags, syringes, vials) **or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test** (see Sterility Tests <71>) **before they are dispensed or administered.** [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Sterility Testing*]

N/a

104. ☐ ☐ **All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins** (see Bacterial Endotoxins Test <85> and Pyrogen Test <151>). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Bacterial Endotoxin (Pyrogen) Testing*]

n/a

105. ☑ ☐ **Does the facility participate in the following** (check all applicable):
☐ Hazardous Drugs ☑ Radiopharmaceuticals ☐ Allergen Extracts as CSPs

Hazardous Drugs

106. ☐ ☐ **All personnel who compound hazardous drugs shall be fully trained** in the **storage, handling, and disposal** of these drugs. This training **shall occur prior to preparing or handling hazardous CSPs**, and **its effectiveness shall be verified by testing specific hazardous drugs preparation techniques**. Such verification **shall be documented for each person at least annually.** This **training shall include didactic overview** of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it **shall include ongoing training for each new hazardous drug that enters the marketplace.** [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]

107. ☐ ☐ **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The training **shall include** at least the following: [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]
- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

108. ☐ ☐ Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

109. ☐ ☐ Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

110. ☐ ☐ Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

111. ☐ ☐ Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

112. ☐ ☐ Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

113. ☐ ☐ **All hazardous drugs shall be prepared in a BSC or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5** (see Table 1) **BSC or CACI shall be placed in an ISO Class 7** (see Table 1) **area that is physically separated** (i.e., a different area from other preparation areas) **and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7** (see Table 1) **or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization.** [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

114. ☐ ☐ If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

115. ☐ ☐ **When closed-system vial-transfer devices** (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) **are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI.** The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

116. ☐ ☐ **Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices.** PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

117. ☐ ☐ Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

118. ☐ ☐ All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

119. ☐ ☐ **Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.** All **personnel** who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs **shall be trained** in appropriate procedures to protect themselves and prevent contamination. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

Radiopharmaceuticals

120. ☑ ☐ For the purposes of this chapter, **radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container (see Injections <1>) shall be designated as, and conform to, the standards for Low-Risk Level CSPs.** These radiopharmaceuticals **shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.** [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

121. ☑ ☐ **Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area.** A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area. [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

Allergen Extracts as CSPs

122. ☐ ☐ Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. **Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met:** [USP-NF Chapter 797- Allergen Extracts as CSPs]

☐ The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
☐ All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.
☐ Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.
☐ Compounding personnel don hair covers, facial hair covers, gowns, and face masks.
☐ Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.
☐ Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.
☐ Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.
☐ Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.
☐ The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).
☐ The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.
☐ Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Sterilization

123. ☐ ☑ Does the facility participate in the following (check all applicable):
☐ Filter Sterilization in an ISO class 5 ☐ Steam Sterilization ☐ Dry Heat Sterilization

124. ☐ ☐ **(Filter Sterilization in an ISO class 5)**
Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. **Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 mm.** They shall be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs). [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

125. ☐ ☐ **The compounding supervisor shall ensure**, directly or from appropriate documentation, that **the filters** are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

126. ☐ ☐ The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

127. ☐ ☐ Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

128. ☐ ☐ Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

129. ☐ ☐ **(Steam Sterilization)**
The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see Steam Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>).**To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmospbere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs.** An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

130. ☐ ☐ Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. **Immediately before filling ampuls and vials that will be steam sterilized, solutious are passed through a filter having a nominal pore size not larger than 1.2 mm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.** [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

131. ☐ ☐ The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see Biological Indicators <1035>) and other confirmation methods such as temperature-sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

132. ☐ ☐ **(Dry Heat Sterilization)**
Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. **Heated filtered air shall be evenly distributed throughout the chamber by a blower device.** [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

133. ☐ ☐ **Dry heat shall be used only for those materials that cannot he sterilized by steam,** when either the moisture would damage the material or the material is impermeable. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility-, Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

134. ☐ ☐ During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

135. ☐ ☐ The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

136. ☐ ☐ The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see Biological Indicators <1035>) and other confirmation methods such as temperature- sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

Finished Preparation Release Checks and Tests

137. ☑ ☐ **All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.** The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed. [USP- NF Chapter 797- Finished Preparation Release Checks and Tests- Inspection of Solution Dosage Forms and Review of Compounding Procedures

138. ☑ ☐ **The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.** When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility*]

139. ☐ ☐ The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum: [UAC R156-17b-614a (3)(g)(i-vi)

n/a

☐ the unique lot number assigned to the batch;
☐ all active solution and ingredient names, amounts strengths and concentrations, where applicable
☐ quantity
☐ beyond use date and time, when applicable
☐ appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and
☐ device-specific instructions, where appropriate.

140. ☑ ☐ All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in Section 58-17b-602 the following: [R156-17b-614a (3)(h)(i)(ii)(iii)
☑ generic name a quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
☑ assigned compounding record or lot number; and
☑ "this is a compounded preparation" or similar language

Packaging and Storage

141. ☑ ☐ Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

142. ☑ ☐ Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

143. ☑ ☐ Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances: [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSP- Storage in Locations Outside Compounding Facilities*]
☑ Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
☑ Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

144. ☑ ☐ **Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs.** CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP- NF Chapter 797- *Finished Preparation Release Checks and Tests- Monitoring Controlled Storage Areas*]

145. ☑ ☐ Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. [USP-NF Chapter 797- Storage and Beyond-use Dating]

Quality Assurance Program

146. ☑ ☐ The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. **Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned.** This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse-events and incident reporting programs. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Education and Training*]

147. ☑ ☐ **A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter.** Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed. Characteristics of a QA program include the following: [USP-NF Chapter 797- *Quality Assurance (QA) Program*]

☑ Formalization in writing;
☑ Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
☑ Description of specific monitoring and evaluation activities;
☑ Specification of how results are to be reported and evaluated;
☑ Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
☐ Delineation of the individuals responsible for each aspect of the QA program.

148. ☑ ☐ A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: [USP-NF Chapter 797- *Responsibilities of Compounding Personnel*]

☑ accuracy and precision of measuring and weighing;
☑ the requirement for sterility;
☑ methods of sterilization and purification;
☑ safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter;
☑ pH;
☑ labeling accuracy and completeness;
☑ BUD assignment;
☑ and packaging and storage requirements.

149. ☑ ☐ Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. **Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.** [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

COMMENTS
(Use an additional sheet if necessary.)

Assisted by PIC Tyrel Einfeldt.

Pharmacy only prepares low-risk radio pharmaceuticals.

Labels for compounded preparations are compliant.

ISO 8 ante-room and ISO 7 buffer room.

Certification records show no concerns.

Cleaning, temperature, and pressure logs are up to date and done daily.

Pharmacy needs to use alcohol based hand scrub prior to donning gloves. Currently using alcohol spray.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: _____ Date of Signature: 12/11/23

Signature of Division Investigator: _____ Date of Signature: 12/11/23

Revised 8/2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: PharmaLogic Salt Lake City, LLC

Pharmacy/Wholesaler License # (if applicable): N/A; new license application

Physical Address: 383 W. Vine Street, Suite 100

City: Salt Lake City State: UT Zip: 84123

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 385-419-4327 Website: www.radiopharmacy.com

Licensing Company Email: SaltLakeCityPharmacy@radiopharmacy.com

Section 2: Personal Information

First: Tyrel Middle: Rick Last: Einfeldt

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addre[redacted]

City: Salt Lake City State: Utah Zip: 84121

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Purdue University		08/09 - 05/13	
Address	City	State	Zip
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Doctorate of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/04 - 05/09	
Address	City	State	Zip
201 Presidents' Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
No degree obtained; pre-pharmacy requisite courses only			

School Name		From - To (MM/YY – MM/YY)	
Olympus High School		08/00 - 05/04	
Address	City	State	Zip
4055 S 2300 E	Holladay	UT	84124
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/17 - Present	[redacted]	Salt Lake City	UT	84121
12/15 - 05/17	[redacted]	Salt Lake City	UT	84109
06/13 - 06/15	[redacted]	Wichita Falls	TX	76309
06/13 - 06/15	[redacted]	Wichita Falls	TX	76308
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PharmaLogic Salt Lake City, LLC			05/23 - Present	
Business Address		**City**	**State**	**Zip**
383 W. Vine St., Suite 100		Salt Lake City	UT	84123
Phone	**Title**		**Number of Employed Hours**	
385-419-4327	PET Pharmacy Manager		1500+	
Description of Duties				
Pharmacist in Charge, repackage and dispense various PET radiopharmaceuticals, performs QC testing on final drug products, participates in internal and external audits, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Huntsman Cancer Institute			12/15 - 05/23	
Business Address		**City**	**State**	**Zip**
2000 Circle of Hope Drive		Salt Lake City	UT	84112
Phone	**Title**		**Number of Employed Hours**	
801-587-7000	Pharmacist in Charge		14,000	
Description of Duties				
Pharmacist in Charge, manufactured various PET radiopharmaceuticals, performed QC testing on manufactured drugs, reviewed and released batches as part of the Quality Assurance team, participated in audits, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Tyrel Einfeldt, **certify that as the designated representative for**

PharmaLogic Salt Lake City, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TE I am at least 21 years of age;
3. TE I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TE I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TE I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TE I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TE I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tyrel Einfeldt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/21/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tyrel Einfeldt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/21/24

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Tyrel Einfeldt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/21/24

Date

Subscribed and Sworn to before me this 21st day of March 2024

Notary Public Signature

SARAH SHANE
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 727263
COMM. EXP. 10/14/2026

(Seal)

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

PharmaLogic Salt Lake City, LLC

EFFECTIVE **11/14/2023**

EXPIRATION **09/30/2025**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13665759-1704 Pharmacy - Class B

Nuclear

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

PHARMALOGIC SALT LAKE CITY, LLC
383 W VINE ST STE 100
SALT LAKE CITY UT 84123

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **11/14/2023**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **PharmaLogic Salt Lake City, LLC**
383 W Vine St Ste 100
Salt Lake City UT 84123

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13665759-1704 **Pharmacy - Class B** **Nuclear**

DBAs: **None Associated**

Form #1

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UTAH DIVISION OF PROFESSIONAL LICENSING
LICENSEE LOOKUP & VERIFICATION SYSTEM

RELATED LINKS & RESOURCES

Details for PharmaLogic Salt Lake City, LLC

License Information

Name:	PharmaLogic Salt Lake City, LLC
City, State, Zip, Country:	Salt Lake City UT 84123 United States
Profession:	Pharmacy
License Type:	Pharmacy - Class B
License Number:	13665759-1704
Obtained By:	Application
License Status:	Active
Original Issue Date:	11/14/2023
Expiration Date:	09/30/2025
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**
Docket and Citation Number(s):	N/A
E-Prescriber:	

Specialty(s):

Nuclear

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For informational assistance, please call DOPL at: (801) 530-6628

Feedback

We'd like to hear from you.

Tell us what you

Give Feedback

Privacy - Terms

DEA Explanation

PharmaLogic Salt Lake City, LLC (UT resident license application pending) is a closed-door nuclear pharmacy that does not order, store, compound, dispense, or otherwise handle controlled substances, therefore a DEA registration is not required for operation of this facility.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: PharmaLogic Salt Lake City, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A; new application

Physical Address: 383 W. Vine Street, Suite 100

City: Salt Lake City State: UT Zip: 84123

Mailing Address (if different from physical address): same as physical

City: State: Zip:

Telephone: 385-419-4327 Toll Free # (NAC 639.708, NRS 639.23286): 877-769-1433

Fax: 385-425-3132 Contact Email: SaltLakeCityPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new application

Supervising/Managing Pharmacist Name (NRS 639.220): Tyrel Einfeldt

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24064

Name of Person with direct knowledge of compounding procedures: Tyrel Einfeldt

Email of Person with direct knowledge of compounding procedures: teinfeld@radiopharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 801-503-2405

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

F-18 FDG - repackaged into unit dose syringes from manufacturer multidose vial
Ga-68 NetSpot - prepared per package insert
Ga-68 Illuccix - prepared per package insert

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

All products are inspected before and after preparation for any visible particles, abnormal color, or turbidity. If the product does not pass visual inspection, the product is quarantined and the compounding pharmacist will reach out to the Quality and Regulatory Department for next steps/investigations as needed.

8. How often do you perform glove fingertip and medial fill testing?

In triplicate as part of onboarding process, then annually thereafter.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

If the observer notes any deviations from the acceptance criteria or procedures for glove fingertip or media-fill testing, the employee is considered to be not qualified and must repeat the qualifications.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Please see SOP 6.02 - Aseptic Qualifications, 6.03 - Gowning, Garbing, and Hand Hygiene, and 7.05 - Network Training for our initial and annual training program for all personnel performing sterile compounding.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see SOP 6.04 - Cleaning of Clean Rooms and SRPAs and 6.05 - Cleaning of Clean LFHs and BSCs for the cleaning of our primary and secondary engineering controls, including frequency and names of approved agents used as cleaners/disinfectants and sporicidals.

12. Who performs the sterile compounding process at your facility?

Authorized nuclear pharmacists (ANPs) perform the sterile compounding process at PharmaLogic Salt Lake City, LLC.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Tyrel Einfeldt, Pharmacist-in-charge

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All products that are delivered/shipped follow DoT regulations and emergency procedures for handling radioactive materials. The delivery process is either initiated after quality control tests are completed, or delivered under quarantine and only released to the customer upon the successful completion of quality control tests.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) Not applicable		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.) Not applicable
1. List the specific high risk sterile products that your facility compounds:
2. What sterilization methods are utilized at your facility?
3. Does your facility utilize biological indicators? ☐ Yes ☐ No
4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Payton Hanby

Name of Person who Completed the Form

Pharmacy Regulatory Affairs Specialist, PharmaLogic Holdings Corp

Title

Signature (copies or stamps not accepted)

4/3/24

Date

Board Use Only	Date Received: 4/16/24 Date Approved: _____ Approved By: _____

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04486	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FP0999637 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Precision Compounding Pharmacy and Wellness

Physical Address: 2657 Merrick Rd

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-833-6262 Toll Free # (NAC 639.708, NRS 639.23286): 855-277-9610

Fax: 516-222-0605 Contact Email: licensingNY@mypcphealth.com

Website: www.mypcphealth.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jeriann Stella

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24122

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jeriann Stella	NV Pharmacist Registration #: 24122
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Christian Stella - Pharmacist	Credentials: NY - 062646	%: 17.783%
Name: Frank Stella - Pharmacist	Credentials: NY - 048186	%: 17.783%
Name: Frank Longo - Pharmacist	Credentials: NY - 038112	%: 17.783%
Name: Richard Longo - Pharmacist	Credentials: NY - 043361	%: 17.783%
Name: Donald Cantalino - Pharmacist	Credentials: NY - 035137	%: 2.244%

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): N/A

Corporation/Organization Name: Precision Compounding Pharmacy & Wellness Inc.

Mailing Address: 2657 Merrick Rd

City: Bellmore State: NY Zip: 11710

Telephone: 516-833-6262 Email: licensingNY@mypcphealth.com

Contact Person Name: Christian Stella

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☑ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/ Owner (title) for Precision Compounding Pharmacy & Wellness (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Christian Stella

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/1/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christian Stella

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

8/1/2024

Date

Board Use Only	Date Received: 9/30/24	Amount: $500-ck 21410

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2021-24

SUPERVISING PHARMACIST
CHRISTIAN STELLA

THIS IS TO CERTIFY

PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
2657 MERRICK ROAD
BELLMORE, NY 11710

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-THIRD DAY OF NOVEMBER, 2021.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF OCTOBER, 2024.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
039041

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

1695

PRECISION COMPOUNDING PHARMACY

Organizational Chart

Name/ Title: Christian Stella – CEO/ Owner [redacted]

Percentage of Ownership: 17.78%

Home Address: [redacted] Merrick, NY 11566

[redacted]

Name/ Title: Richard Longo – CFO [redacted]

Percentage of Ownership: 17.78%

Home Address: [redacted] Garden City, NY 11530

[redacted]

Name/ Title: Frank Stella – COO [redacted]

Percentage of Ownership: 17.78%

Home Address: [redacted] Merrick, NY 11566

[redacted]

Name/ Title: Frank Longo – Secretary [redacted]

Percentage of Ownership: 17.78%

Home Address [redacted] Bellmore, NY 11710

[redacted]

Name/ Title: Peregrine Select Fund, L.P.

Percentage of Ownership: 12.08%

Business Address: 649 Mission St #5th San Francisco, CA 94105

Phone Number: 415-655-4965

Email: dave@rightsidecapital.com

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, BRENDAN C. HUGHES, Acting Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
DOS ID Number:	5670689
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	12/12/2019
Statement Status:	CURRENT
Statement Due Date:	12/31/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on May 17, 2024 at 11:10 A.M.

Brendan C. Hughes

BRENDAN C. HUGHES
Acting Secretary of State

Authentication Number: 100005754344 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

New York State Department of State
Division of Corporations, State Records and Uniform Commercial Code

COPY REQUEST/CERTIFICATE OF STATUS RECEIPT

PRECISION COMPOUNDING PHARMACY AND WELLNESS
2657 MERRICK ROAD
BELLMORE NY 11710

DATE: 05/17/2024 **TRANSACTION NUMBER:** 202405170001248

ENTITY INFORMATION:

ENTITY NAME:	PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
DOS ID:	5670689
DATE OF INITIAL DOS FILING:	12/12/2019

REQUESTED SERVICES:	NUMBER REQUESTED:	FEE:
UNCERTIFIED COPY($5.00)		$0.00
CERTIFIED COPY($10.00)		$0.00
CERTIFICATE OF STATUS - SHORT FORM($25.00)	1	$25.00
CERTIFICATE OF STATUS - LONG FORM($25.00)		$0.00
EXPEDITED HANDLING		$25.00

TOTAL PAYMENTS RECEIVED:	$50.00
CASH:	$0.00
CHECK/MONEY ORDER:	$0.00
CREDIT CARD:	$50.00
DRAWDOWN ACCOUNT:	$0.00
REFUND DUE:	$0.00

REQUESTED COPY	FILE DATE	FILE NUMBER

DOS-1025 (04/2007)

PRECISION
COMPOUNDING
PHARMACY

Name/ Title: Donald Cantalino – Director/ Shareholder [redacted]

Percentage of Ownership: 2.24%

Home Address: [redacted] Neal Path South Setauket, NY 11720

[redacted]

Name/ Title: Comeback Capital, LP – C2 – Director/Shareholder

Percentage of Ownership: 2.08%

Business Address: PO Box 3217 Seattle, WA 98114

Email: portfolio@angelist.com

Name/ Title: Integral Venture Fund I LP – Director/ Shareholder

Percentage of Ownership: 2.08%

Business Address: 233 Ellis Parkway Piscataway, NJ 08854

Email: larry@integralprovate.com

Name/ Title: Justin Kahn – Director/ Shareholder [redacted]

Percentage of Ownership: 0.83%

Home Address: [redacted] Bryan Ave Salt Lake City, UT 84108

[redacted]

Name/ Title: ESOP (Employee Stock Option Pool) – Director/Shareholder

Percentage of Ownership: 9.57%

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP0999637	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-06-2024

PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
D/B/A PRECISION COMPOUNDING PHARMACY
2657 MERRICK RD
BELLMORE, NY 117105716

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP0999637	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-06-2024

PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
D/B/A PRECISION COMPOUNDING PHARMACY
2657 MERRICK RD
BELLMORE, NY 117105716

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
DOS ID Number:	5670689
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	12/12/2019
Statement Status:	CURRENT
Statement Due Date:	12/31/2021

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on March 29, 2022 at 02:25 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100001302896 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

PRECISION COMPOUNDING PHARMACY & WELLNESS INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	PRECISION COMPOUNDING PHARMACY & WELLNESS INC.
Trade Name	PRECISION COMPOUNDING PHARMACY
Street Address	2657 MERRICK ROAD BELLMORE NY 11710
Registration No	039041
Date First Registered	November 23, 2021
Registration Begins	November 01, 2024
Registered Through	October 31, 2027
Supervisor	062646 - STELLA CHRISTIAN FRANK
Establishment Status	Active
Successor	NONE

NYS ED

September 10, 2024 03:46 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=039041&professionCode=020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Precision Compounding Pharmacy and Wellness

NV Pharmacy or Outsourcing facility license # (if applicable): PH04486

Physical Address: 2657 Merrick Road

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-833-6262 Toll Free # (NAC 639.708, NRS 639.23286): 855-277-9610

Fax: 516-222-0605 Contact Email: licensingNY@mypcphealth.com

Website: mypcphealth.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jeriann Stella

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24122

Name of Person with direct knowledge of compounding procedures: Jeriann Stella

Email of Person with direct knowledge of compounding procedures: [redacted]@gmail.com

Telephone of Person with direct knowledge of compounding procedures: 516-833-6262

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ■ Low ■ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Testosterone Cypionate 200mg/mL Grapseed Oil Injection Solution - #5mL Vial & #10mL Vial

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ■ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

Vials are inspected against a blacklight box and inspected for visual particulates, etc.

8. How often do you perform glove fingertip and medial fill testing?

Initially and every 6 months thereafter.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

They are to undergo retraining for an additional 2 weeks, then retest. If they fail a second time, they will not be given a third chance and will not be deemed competent to engage in sterile compounding.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

See attached SOP 8.025 Sterile Compounding Personnel Training and Education.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached SOP 8.019 Sterile Compounding Area Cleaning Log.

12. Who performs the sterile compounding process at your facility?

Sterile Compounding Pharmacists and sterile compounding technicians.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The designated person as per USP.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see attached SOP 12.001 Telehealth Compound Drug Shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? LAFW and BSC.		
2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☒ No
4. Will you be compounding with antineoplastic HDs or HD API?	☒ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? - Safe handling of hazardous drugs including wearing proper PPE, do not crush tablets, do not open capsules, and wear gloves when handling drugs. - Proper disposal via a take-back program or pharmacy. Do not throw medication away or flush it. - Store medication in a safe place, away from light. Keep out of the reach of pets and children. - What to do in the case of a spill. - A toll-free number to call in case of an emergency or for questions.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Please see attached 8.025 Sterile Compounding Personnel Training and Education & SOP 9.003 Hazardous Drug Personnell Training.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Medication Name and Dosage Form -- Strength and/or Size
- Sermorelin 2mg/mL Vials -- 5mL
- Testosterone Cypionate (Grapeseed Oil) 200mg/mL Vials -- 5mL|10mL
- Semaglutide 2.5mg Methylcobalamin 100mcg/mL Vials -- 1mL|2mL|3mL|4mL|5mL
- Tirzepatide 5mg/0.5mL Vials -- 1mL|2mL|3mL|4mL|5mL|6mL
- Liraglutide 6 mg Methionine 2mg/mL Vials -- 6mL
- Methionine 15mg Inositol 50mg Choline Chloride 100mg Vials -- 10mL
- Methylcobalamin 1mg/mL Vials -- 10mL
- Glutathione 200mg/mL Vial -- 10mL
- Methylcobalamin 1mg/mL Vial -- 10mL
- Nicotinamide Adenine Dinucleotide (NAD+) 200mg/mL Vial -- 2.5mL|5mL

2. What sterilization methods are utilized at your facility?

Filtration

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christian Stella
Name of Person who Completed the Form

Owner/CEO
Title

Signature (copies or stamps not accepted)

8/1/2024
Date

Board Use Only	Date Received: 9/30/24 Date Approved: _____ Approved By: _____

Drug	Form	Strength
Diazepam	Suppository	5mg
Diltiazem	Cream	2%
Diltiazem / Lidocaine	Cream	2% / 5%
Diltiazem / Lidocaine / Hydrocortisone	Cream	2% / 5% / 2.3%
Nifedipine	Ointment	0.20%
Nifedipine / Lidocaine	Cream	0.4% / 5%
Nitroglycerin	Cream	0.20%
Ivermectin	Tablet	24mg
Acyclovir	Cream	10%
Clindamycin / Tretinoin / Niacinamide	Cream	1.25% / 0.04% / 4%
Fluocinoline Acetonide / Hydroquinone / Tretinion Acid	Cream	0.01% / 6% / 0.1%
Hydroquinone	Cream	8%
Hydroquinone / Ascorbic Acid / Niacinamide	Cream	5% / 1% / 4%
Hydroquinone / Tretinoin / Hydrocortisone	Cream	4% / 0.025% / 1%
Tretinoin / Azaleic Acid / Niacinamide	Cream	0.04% / 5% / 4%
Finasteride / Minoxidil	Spray Solution	0.1% / 5%
Finasteride / Minoxidil	Spray Solution	0.1% / 7%
Finasteride / Minoxidil / Progesterone / Fluocinolone	Spray Solution	0.1% / 5% / 0.5% / 0.05%
Minoxidil	Capsule	0.25mg
Minoxidil	Spray Solution	6%
Minoxidil	Capsule	0.625mg
DHEA / Pregnenolone	Capsule	25mg / 25mg
DHEA / Pregnenolone	Capsule	50mg / 50mg
Estradiol	Capsule	1mg
Estriol	Cream	1mg/ml
Estriol / Testosterone	Cream	1mg / 0.5mg/ml
Progesterone	Cream	100mg/ml
Progesterone	Cream	200mg/ml
Progesterone	Suppository	200mg
Progesterone IR	Capsule	50mg
Progesterone IR	Capsule	100mg

Progesterone IR	Capsule	200mg
Progesterone IR	Capsule	300mg
Progesterone IR	Capsule	400mg
Progesterone SR	Capsule	100mg
Progesterone SR	Capsule	200mg
Testosterone	Cream	20mg/ml
Testosterone	Cream	80mg/ml
Testosterone	Cream	200mg/ml
Testosterone	Sublingual Tablet	50mg
Testosterone Cypionate	Injection	200mg/ml
Glutathione	Injection	200mg/ml
Glutathione	Nasal Spray	200mg/ml
L-Carnitine	Injection	500mg/ml
Methylcobalamin	Injection	1mg/ml
Methylene Blue	Capsule	50mg
NAD+	Cream	10%
NAD+	Injection	200mg/ml
NAD+	Nasal Spray	300mg/ml
Oxytocin	Nasal Spray	50IU/spray
Oxytocin	Troche	50IU
PT-141	Nasal Spray	10mg/ml
Rapamycin	Tablet	10mg
Sermorelin	Injection	200mg/ml
Sildenafil / Pentoxifylline / Ergoloid Mesylates	Cream	1% / 2% / 0.05%
Vitamin D3	Injection	100,000 IU/ml
Anastrozole	Tablet	1mg
Clomiphene	Tablet	56mg
Enclomiphene	Capsule	6.25mg
Enclomiphene	Capsule	25mg
Nandrolone	Injection	200mg/ml
Ketamine	RDT	50mg

Ketamine	RDT	100mg
Ketamine	RDT	150mg
Ketamine	RDT	200mg
Ketamine	RDT	250mg
Ketamine	RDT	300mg
Ketamine	RDT	350mg
Ketamine	RDT	400mg
Ketamine	RDT	450mg
Ketamine	RDT	500mg
Ketamine	Troche	50mg
Ketamine	Troche	100mg
Ketamine	Troche	150mg
Ketamine	Troche	200mg
Ketamine	Troche	250mg
Ketamine	Troche	300mg
Ketamine	Troche	350mg
Ketamine	Troche	400mg
Ketamine	Troche	450mg
Ketamine	Suppository	100mg
Ketamine	Suppository	150mg
Ketamine	Suppository	200mg
Ketamine	Suppository	250mg
Ketamine	Suppository	300mg
Ketamine	Suppository	350mg
Ketamine	Suppository	400mg
Naltrexone	Tablet	1mg
Naltrexone	Tablet	1.5mg
Naltrexone	Tablet	3mg
Naltrexone	Tablet	4.5mg
Gabapentin / Amitripyline / Baclofen / Lidocaine	Cream	6% / 2% / 2% / 2%
Ketamine / Lidocaine	Cream	15% / 15%

Naltrexone	Tablet	50mg
Methionine / Inositol / Choline Chloride / Methylcobalamin	Injection	15mg / 50mg / 100mg / 1mg/ml
Naltrexone / B6 / Buproprion	Capsule	17mg / 5mg / 180mg
Semaglutide / Methylcobalamin	Injection	2.5mg / 0.1mg/ml
Tirzepatide	Injection	5mg/0.5ml
Betamethasone / Mupirocin / Miconazole	Cream	0.1% / 2% / 2%
Boric Acid	Suppository	600mg
Boric Acid / Clotrimazole / Hydrocortisone / Lactrobacillus	Suppository	300mg / 200 mg / 20mg / 100mg
Boric Acid / Hydrocortisone / Lactobacillus	Suppository	400 mg/ 20 mg/ 100 mg
Boric Acid / Lactobacillus	Suppository	100 mg
Boric Acid / Metronidazole / Lactobacillis	Suppository	200mg / 300mg / 100mg
Clindamycin / Nystatin / Vitamin E	Suppository	100mg /100,000IU /200IU
Clindamycin / Vitamin E	Suppository	100mg / 200IU
Clotrimazole / Boric Acid / Acidophilus Lactobacillus	Suppository	200mg / 400mg / 100mg
Hyaluronic Acid /Vitamin A / Vitamin E + Aloe	Cream	5mg / 1mg/ 400IU/mL
Lidocaine / Amitriptyline	Cream	5% / 2%
Metronidazole / Clindamycin	Suppository	350mg / 100mg
Metronidazole / Clindamycin / Hydrocortisone / Nystatin	Suppository	350mg / 100mg / 20mg / 100,000IU
Metronidazole / Nystatin	Suppository	500mg / 100,000IU
Nystatin / Ascorbic Acid	Cream	100,000 IU / 25mg/mL

Title: Sterile Compounding Area Cleaning Log **SOP # 8.019**
Version # 1.0
Written & Reviewed by: Connor Longo, PharmD. ***Date:4/9/2024***
Authorized by: Christian Stella, PharmD. ***Date:4/9/2024***

1) PURPOSE

a) The purpose of this procedure is to document cleaning and disinfection of sterile compounding areas.

2) SCOPE

a) This procedure applies to all compounding personnel that perform cleaning/disinfection.

3) RESPONSIBILITY

a) All personnel making entries in the log are responsible for following the requirements of this SOP.

4) REFERENCES

a) SOP 10.002 "Good Documentation Practices (GDP)"

5) DEFINITIONS

a) LOG- a document describing daily, monthly, or annual cleaning and maintenance of lab equipment, room temp/humidity monitoring or other.

6) FREQUENCY

a) After maintenance and cleaning activities per the appropriate SOP.

7) EQUIPMENT & SUPPLIES

N/A

8) GENERAL INFORMATION

a) Surfaces are non-porous allowing for easier cleaning.

9) PROCEDURE

a) Entries in the log will be made at the time the activity occurred and in chronological order. Entries must include the initials of the person completing the task.

b) All entries made in the log should be in compliance with "Good Documentation Practices (GDP)".

c) The Pharmacist-in-charge or their designee shall review logs at *least* monthly.

i) The Pharmacist-in-charge or designee will sign and date the log certifying that the review was performed, and any deficiencies encountered were corrected.

ii) If any blanks are found, all personnel are to be contacted. All are to be retrained in the importance of proper documentation. All logs will be reviewed by the PIC *daily* for the next month to ensure proper documentation and that personnel have been adequately retrained.

d) Entries made in the log must be in compliance with all applicable SOPs for the task being performed.

e) To note: there is a hazardous and a non-hazardous sterile compounding laboratory.

i) In the non-hazardous laboratory there is a Laminar Air Flow Workstation. Drug powders and materials are stored in the ante room.

ii) In the hazardous laboratory there is a Class II A2 Biological Safety Cabinet. Designated hazardous drugs are stored in the hazardous laboratory with a designated powder containment hood, scale, and hot plate/mixer.

f) When cleaning the following PPE is to be used:

i) Hair/beard covers

ii) Face mask

iii) Shoe covers (two pairs if going into the hazardous laboratory)

iv) Disposable gown

v) Gloves (two pairs if going into the hazardous laboratory)

vi) Goggles

vii) Powered air purifying respirator (PAPR) mask

g) The EPA Registered one-step cleaning and disinfecting agent is PeridoxRTU

h) The Sporicidal Agent is PeridoxRTU

i) Hard copy logs should be returned to the Pharmacist-in-charge or their designee for archiving.

j) Any essential materials that are particle shedding (i.e. a refrigerator) are to be placed near returns to avoid any particles from shedding into the clean room.

k) If any contamination is noticeably visible in the lab, all compounding is to stop until the lab undergoes cleaning, deactivation, decontamination, and sterilization and is deemed by the PIC as acceptable for active compounding use.

l) The above is to occur if there is any constriction being done in the lab or directly outside the lab.

10) ATTACHMENTS

Attachment 1 – Sterile Non-Hazardous Compounding Area Cleaning Log
Attachment 2 – Sterile Hazardous Compounding Area Cleaning Log
Attachment 3 – Ante Room Cleaning Log
Attachment 4 – Daily Calibration Log
Attachment 5 - Cleaning Checklist and Log

Attachment 1:
Sterile Non-Hazardous Compounding Area Cleaning Log

Month/Year:_____

Note: Write initials in the appropriate box

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily	Clean/Disinfect Per SOP 8.019																														
LAWF #1																															
LAWF #2																															
Reusable Tools and PPE																															
Handles of cleaning tools																															
Work bench																															
Pass Through #1																															
Floors																															
Take out trash																															
Monthly	Clean/Disinfect and Apply Sporicide Per SOP 8.019																														
LAWF #1																															
LAWF #2																															
Work Bench																															
Ceilings																															
Pass Throughs																															
Floors																															
Walls																															
Storage																															

***NOTE: Any day in the grid that is not associated with a compounding day of the reporting month, place one diagonal line through the cell in the grid.

QA Review: Signature: _____ Date: _____

EPA Registered one-step cleaning and disinfecting agent used: _____

Sporicidal Agent: _____

Attachment 2:
Sterile Hazardous Compounding Area Cleaning Log

Month/Year:_____

Note: Write initials in the appropriate box

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily	Clean/Disinfect Per SOP 8.019																														
BSC																															
Mixing Hood HD																															
Work Bench #1																															
Work Bench #2																															
Handles of cleaning tools																															
Reusable Tools (via Autoclave) and PPE																															
Pass Through																															
Hot Plate/Magnetic Stirrer																															
Balance																															
Floors																															
Take out trash																															
Monthly	Clean/Disinfect and Apply Sporicide Per SOP 8.019																														
BSC																															
Mixing Hood HD																															
Pass Throughs																															
Work Bench #1																															
Work Bench #2																															
Floors																															
Walls/Ceilings																															

***NOTE: Any day in the grid that is not associated with a compounding day of the reporting month, place one diagonal line through the cell in the grid.

QA Review: Signature:_____ Date:_____

EPA Registered one-step cleaning and disinfecting agent used this month: _____

Sporicidal Agent used this month: _____

Attachment 3: Ante Room Cleaning Log

Month/Year:_____

Note: Write initials in the appropriate box

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily	Clean/Disinfect Per SOP 8.019																														
Mixing Hood Non-HD #1																															
Mixing Hood Non-HD #2																															
Balance																															
Hot Plate/Magnetic Stirrer																															
Handles of cleaning tools																															
Reusable Tools and PPE																															
Anteroom sink																															
Pass Throughs																															
Floors																															
Take out trash																															
Work Bench #1																															
Work Bench #2																															
Work Bench #3																															
Bins																															
Gowning Bench																															
Turn off oven																															
Monthly	Clean/Disinfect and Apply Sporicide Per SOP 8.019																														
Mixing Hoods Non-HD																															
Anteroom Sink																															
Work Benches																															
Pass Throughs																															
Floors																															
Walls/Ceilings																															
Shelves/Storage																															
Gowning Bench																															

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Refrigerator	

***NOTE: Any day in the grid that is not associated with a compounding day of the reporting month, place one diagonal line through the cell in the grid.

QA Review: Signature: _____ Date: _____

EPA Registered one-step cleaning and disinfecting agent used this month: _____

Sporicidal Agent used this month: _____

Attachment 4:

Daily Calibration Log:

***NOTE: Any day in the grid that is not associated with an actual day of the reporting month, place one diagonal line through the cell in the grid

Month: _____ **Scale:** Non-hazardous

		Day of the month																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Weight	0.001 mg																															
	0.002 mg																															
	0.012 mg																															
	0.022 mg																															
	0.1 mg																															
	0.2 mg																															
	0.5 mg																															
	1 gm																															
	2 gms																															
	5 gms																															
	10 gms																															

	20 gms																													
	50 gms																													
	100 gms																													
	200 gms																													
	500 gms																													

Reviewed By: _____ **Date:** _____

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Daily Calibration Log:

***NOTE: Any day in the grid that is not associated with an actual day of the reporting month, place one diagonal line through the cell in the grid

Month: _____ **Scale:** Hazardous

		Day of the month																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Weight	0.001 mg																															
	0.002 mg																															
	0.012 mg																															
	0.022 mg																															
	0.1 mg																															
	0.2 mg																															
	0.5 mg																															
	1 gm																															
	2 gms																															
	5 gms																															
	10 gms																															

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	20 gms																														
	50 gms																														
	100 gms																														
	200 gms																														
	500 gms																														

Reviewed By: _____ **Date:** _____

Attachment 5: Cleaning Checklist and Log

Date	Daily			Weekly			Monthly
	ISO 5 Workstations	Compounders	Floors	Walls & Windows	Shelving & Bins	Carts & Chairs	Ceilings

Daily Compound Start ISO 5 Cleanroom Cleaning Checklist

☐ Mix cleaning and disinfecting agents updating log

☐ Clean ISO Class 5 workstations including compounders with designated agents

☐ Disinfect ISO Class 5 workstations including compounders with designated agents

Daily Compound During Compounding ISO 5 Cleanroom Cleaning Checklist

☐ Clean ISO Class 5 between compounding activities

☐ Clean ISO Class 5 every 30 minutes while compounding

☐ Clean ISO Class 5 after any spills

☐ Clean ISO Class 5 when surface contamination is suspected

Daily Compound Finish ISO 5 Cleanroom Cleaning Checklist

☐ Mix cleaning and disinfecting agents updating log

☐ Empty waste receptacles and replace liners (daily or as often as needed)

☐ Remove hazardous-waste receptacles

☐ Remove biohazardous materials

☐ Clean sinks, countertops, cart tops, stool tops, and sharps containers

☐ Clean ISO Class 5 workstations including compounders with designated agents, noting any rotation of solutions

☐ Disinfect ISO Class 5 workstations including compounders with designated agents, noting any rotation of solutions

☐ Mop floors utilizing a figure 8 pattern to reduce leaving behind particles

Weekly ISO 5 Cleanroom Cleaning Checklist

☐ Mix cleaning and disinfecting agents updating log

☐ Empty waste receptacles and replace liners

☐ Remove hazardous-waste receptacles

☐ Remove biohazardous materials

☐ Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom

☐ Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers

☐ Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers

☐ Empty, clean, and sanitize storage shelving and bins

☐ Clean ISO Class 5 workstations including compounders with designated agents, noting any rotation of solutions

☐ Disinfect ISO Class 5 workstations including compounders with designated agents, noting any rotation of solutions

☐ Mop floors utilizing a figure 8 pattern to reduce leaving behind particles ☐ Update cleaning log

Monthly ISO 5 Cleanroom Cleaning Checklist

☐ Mix cleaning and disinfecting agents including a sporicidal agent (alternating Peridex and Decon-Spore 200 Plus) for the monthly cycle updating log

☐ Empty waste receptacles and replace liners

☐ Remove hazardous-waste receptacles

☐ Remove biohazardous materials

☐ Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers

☐ Empty, clean and sanitize storage shelving and bins

☐ Clean ceilings of all controlled environments

☐ Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom

☐ Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers

☐ Clean and sanitize interior and exterior of refrigerators and incubators (not kept in controlled environments)

☐ Clean ISO Class 5 workstations (including compounders residing in the workstations)

☐ Disinfect ISO Class 5 workstations including compounders with designated agents, noting any rotation of solutions

☐ Mop floors utilizing a figure 8 pattern to reduce leaving behind particles

Signature of Designated Person

Date Reviewed

Title: Sterile Compounding Personnel Training and Evaluation **SOP # 8.025**
Version # 1.1
Written & Reviewed by: Connor Longo, PharmD. ***Date: 12/11/2023***
Authorized by: Christian Stella, PharmD. ***Date: 12/11/2023***

1) PURPOSE

a) To establish a training and evaluation program for sterile compounding personnel.

2) SCOPE

a) This SOP applies to all sterile compounding personnel.

3) RESPONSIBILITY

a) The pharmacist in charge or their designee will be responsible for implementation of this procedure.

4) REFERENCES

a) USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

5) DEFINITIONS

a) N/A

6) FREQUENCY

a) Personnel must receive training and competency assessments as required by this SOP prior to independently preparing sterile compounded. Note that certain requirements in this SOP must be completed annually and others every six months.

7) EQUIPMENT & SUPPLIES

a) N/A

8) GENERAL INFORMATION

a) This training and evaluation program is designed to ensure personnel:
   i) Read and understand USP<797> and other applicable standards and relevant literature
   ii) Understand and know how to interpret Safety Data Sheets (SDS) and if applicable, Certificates of Analysis.
   iii) Read and understand procedures related to their compounding duties.
   iv) Ensure personnel are trained and competent in the following compounding skills:
      (1) Hand hygiene

(2) Garbing

(3) Cleaning and disinfecting

(4) Calculations, measuring and mixing

(5) Aseptic technique

(6) Achieving and/or maintaining sterility and pyrogenicity

(7) Use of equipment

(8) Documentation of the compounding process (e.g. master formulation and compounding records)

(9) Principles of high efficiency particular air (HEPA)-filtered unidirectional airflow within the ISO-Class 5 Area.

(10) Proper use of primary engineering controls

(11) Principles of movement of materials and personnel within the compounding area

(12) Measuring and mixing

v) For personnel that handle or compound with hazardous drugs, training and evaluation as required by SOP 9.003 Hazardous Drug Personnel Training

vi) Personnel must complete this training program and demonstrate proficiency before compounding independently.

vii) Personnel involved in the compounding process will be evaluated on their physical ability to perform the assigned compounding responsibility without compromising the integrity of the compound. This will include handicaps that may affect the ability to aseptically compound, along with appropriate dexterity skills, and any illness or injury.

9) PROCEDURE

a) Upon the start of employment all sterile compounding, personnel will receive:

i) An introduction to management and compounding laboratory staff

ii) Tour of facility including but not limited to:

(1) Break areas and restrooms

(2) Operation of phones and other telecommunications equipment

iii) Orientation to designated compounding area and compounding equipment

iv) Review the goals of the compounding laboratory

v) Daily job responsibilities

b) Sterile compounding personnel must complete the following requirements at the start of employment and annually thereafter:

i) Narcotics and controlled substances - Drug Diversion Training by reviewing SOP 1.005 and watching the required video.

ii) Training requirements:

(a) Watch OSHA video on reading SDS: Watch SDS Video https://www.youtube.com/watch?v=vCI7XXExs7s

(b) Read and understand all SOPs related to their duties. Review of applicable SOPs will be documented on Attachment F, "SOP and USP<797> Acknowledgement".

(c) Read and understand USP Chapter <797> "Pharmaceutical Compounding – Sterile Preparations". Review of applicable SOPs will be documented on Attachment F, "SOP and USP<797> Acknowledgement".

(d) Trainer will explain HD list, location of HD list, and how to access the HD list

(e) Trainer will demonstrate location and use of eye washes and/or showers and spill kits

(f) Trainer will demonstrate location and use of the autoclave and dry heat oven as well as the specific biological indicators that confirm each machine's proper functioning.
(i) SOP 5.018 Equipment and Facility Maintenance is to be used to document quality assurance checks and accuracy of the machinery.
(ii) If the biological indicator shows failure of the machine, a work order (found in SOP 5.018) is to be initiated and presented to the Chief Compliance Officer (CCO). The CCO is to determine if this can be fixed internally or externally. The machine must be functioning properly before being used.

(g) Trainer will demonstrate identify proper reusable tools, I.e. what tools are to be reused, of what material they are to be composed of in order to be reusable, how to properly clean and sterilize in order to be reused, how to identify proper condition to be reused (I.e. no cracks or chips).
(i) Any tool that does not identify to be proper in order to be reusable are to be discarded of.

(h) If applicable to their job duties, education related interpretation and use of Certificates of Analysis (COAs)

(i) Trainer(s) will observe and guide personnel throughout the training process related to their job duties. The trainer or an experienced employee will serve as the instructor using hands-on training, SOPs, and other documents as appropriate.
(i) The trainer will observe and guide the employee throughout the training process using the Attachment E – Sterile Training Documentation
(ii) The trainer will require the employee to repeat procedures independently under direct supervision.
(iii) Personnel may perform procedures without direct supervision only after demonstrating understanding and competency.

(j) Training related to the above requirements will be documented on Attachment C - Sterile Training Documentation.

(k) Prior to entering sterile compounding areas: In order to ensure personnel can enter sterile compounding areas in a manner that reduces the risk that they will contaminate surfaces and compounded sterile preparations during training, the first two training and competency tests to be performed are:
(i) Hand washing per the established procedure
(ii) Garbing and gowning per the established procedure
(iii) Competency in performing these two procedures will be assessed by:
a. Attachment A - Gloved Fingertip and Thumb Sampling Procedures – Initial and Annual
b. Initial sampling - initial competency evaluation, including visual observation and gloved fingertip and thumb sampling on both hands, three separate times. Each fingertip and thumb evaluation must occur after performing a separate and complete hand hygiene and full garbing procedure. Failure of this test is indicated by a CFU count (total number of CFU from both hands) of >0.
c. Ongoing-every six months: gloved fingertip and thumb sampling after performing a media fill test.
d. Hand Hygiene and Garbing Observational Competency: completing an acceptable observational competency per Attachment B
e. If the evaluator determines that the employee's performance is deficient, or if gloved fingertip testing fails (>0 CFU) the evaluator and the employee will develop a written action plan for correction.

(l) Following on the job training in aseptic compounding, aseptic technique observational competency per Attachment C, Aseptic Technique Observational Competency.
(m) Media fill testing in accordance with SOP 18.021, Sterile Compounding Media Fill Test
(n) Cleaning and disinfection of sterile compounding areas in accordance with the appropriate SOPs in section 6. Competency assessment in accordance with "Performance Audit - Sterile Cleaning & Disinfecting Lab Procedures"
(o) Sterilization and depyrogenation procedures in accordance with the appropriate SOPs in Section 8. Competency assessment in accordance with "Performance Audit - Sterilization & Depyrogenation."

c) Sterile compounding personnel must complete the following requirements initially every six months:
i) Media fill testing in accordance with SOP 18.021, Sterile Compounding Media Fill Test
ii) Post media fill gloved fingertip testing per Attachment D - Post Media Fill Gloved Fingertip Testing
iii) If Media Fill Testing or gloved fingertip testing fails (>3 CFU) the evaluator and the employee

will develop a written action plan for correction.

d) **Sterile compounding personnel must complete the following requirements annually:**
   i) Aseptic Technique Observational Competency
   ii) Performance Audit - Sterile Cleaning & Disinfecting Lab Procedures
e) Personnel who do not meet all training requirements and pass the appropriate competency assessments will not compound independently until they do so. A written action plan for correction will be developed and documented in the employee's profile.
f) The above stated will also occur if any serious gaps have been identified in personnel's aseptic techniques in addition to complete retraining of all aspects of compounding.
g) Viable testing will occur monthly which includes air and surface sampling.

10) ATTACHMENTS

Attachment A: Performance Audit of Hand Hygiene and Garbing for Sterile Compounding

Attachment B: Aseptic Technique Observational Competency

Attachment C: Sterile Training Documentation

Attachment D: Viable Air and Surface Testing

Attachment E: SOP AND USP<795> Acknowledgement

Attachment A:

Performance Audit of Hand Hygiene and Garbing for Sterile Compounding - Initial and Annual

Employee Name:
Position:

Directions: A qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if not applicable or N/O if activity was not observed. The person assessed is immediately informed of all unacceptable activities and shown specific corrections.

Entering Compounding Area

Item	Yes	No
Presents in a clean appropriate attire and manner. Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests, jewelry). Does not enter if sick or exposed to illness.		
Removes all cosmetics because they shed flakes and particles.		
Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails and extenders) must not be worn.		
Wipes eyeglasses if worn.		
Does not wear earbuds or headphones. Does not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.		
Brings no food of drinks into ante-area or buffer areas		
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.		
Dons shoe covers one at a time, placing the covered or designated show on the clean side of the line of demarcation as appropriate.		
Dons beard cover if necessary.		
Dons head cover assuring that all hair is covered.		
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.		
Dries hands and forearms using lint-free towel		
Selects appropriately sized gown examining for tears or other defects		
Dons gown and ensures full closure		
Gown sleeves do not contact floor or other surfaces during donning		
Enters buffer room without contaminating hands		
Disinfects hands again using waterless alcohol-based hand rub and allows hands to dry thoroughly without waving or blowing prior to donning sterile gloves		
Dons appropriately sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips		
Examines gloves to ensure that there are no defects, holes, or tears.		

Leaving the Buffer Room

Item	Yes	No
Removes personal protective equipment on the dirty side of the ante area		
Removes gloves and performs hand hygiene		
Removes gown and discards it, or hangs it on hook if it is clean and can be used the same shift		
Removes and discards mask, head cover, and beard cover prior to leaving compounding lab.		
Removes shoe covers when leaving the compounding lab		

Evaluator Comments

Signature of Person Assessed Printed Name Date

Signature of Qualified Evaluator Printed Name Date

Attachment B:

Aseptic Technique Observational Competency - Initial and Annual

Employee Name:
Position:

Presterilization Operations

Item	Yes	No
Removes all materials to be used in the Cleanroom from shipping containers that may generate particles, e.g., cardboard or other particulate generating materials.		
Disinfects all items as they cross the line of demarcation or are placed in pass through.		
Ensures that the cart or conveyance that is used to transport components into the cleanroom do not cross the line of demarcation separating the "Clean" side of the Ante area from the "Dirty" side		
Ensures that Immediately before any item is introduced into the clean side of the anteroom or placed into pass-throughs, that the supplies are decontaminated wiping with a non-linting wipe saturated in a sporicidal agent, EPA-registered disinfectant or SIPA. Ensures minimum contact time of the disinfectant according to the manufacturers' directions, validation studies or published data.		
Verifies all necessary supplies for completing the compounding operation are available in the compounding area.		
Verifies all ingredient quantities and expiration dates.		
Performs all presterilization operations in a minimum ISO-8 environment		
Transfers all required materials to primary engineering control in a manner that prevents contamination.		

Sterile Compounding

Disinfects primary engineering control (PEC) and surfaces and equipment per SOPs prior to compounding		
Properly sterilizes all reusable materials prior to compounding in the autoclave. Once sterilized, items are to be properly protected from contamination (i.e., saran wrap open lids) for transportation into the PEC. Uses a biological indicator to ensure properly functioning of the machine used to sterilize all reusable equipment.		
Immediately before any item is introduced into the PEC, wipes items with SIPA using low lint wipers and allows to dry.		
While sterile compounding, routinely disinfects gloves with sterile 70% IPA after touching items or surfaces that may contaminate them, an after re-entering the PEC with hands.		
Verifies amounts/volumes to add using the compounding record.		
Works neatly with all materials in a proper arrangement in the PEC. Does not block first air.		
Ensures syringes, needles, tubing and other sterile disposables remain in their individual packaging and are only opened in the PEC.		
Selects the smallest syringe that can hold a desired amount of solution shall be used in order to maximize accuracy.		
Never be touches: (1) the tip and (2) in inside of the plunger of syringes, or (1) hub or (2) needle.		
Performs sterile manipulations only in the DCA.		

Maintains critical sites in first air. Does not block first air during compounding operations		
Avoids: (a) Leaning into or over the work area (b) Blocking "First Air" between sanitized and/or open containers. (c) Resting hands or forearms on the work area. (d) Coughing over the work area. (e) Rapid movement in the direct compounding area (DCA). (g) Using a PEC as a storage space when not in use. (i) Performing any activities unrelated to compounding		
Disinfects stoppers, injection ports and ampoules with sterile 70% IPA and allows sufficient time to dry.		
Attaches needles to syringe without contact contamination. Avoids touching syringe barrel.		
Does not pick up items any items dropped on floor until sterile compounding operations are complete.		
Punctures vial stoppers and spikes infusion ports without contact contamination. Performs needle punctures with bevel up.		
Applies sterile 70% IPA to the horizontal work surface of the PEC at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding is not be disrupted and the work surface of the PEC is disinfected immediately after compounding.		
Checks the expiration dates and/or color indicators when using autoclaved equipment.		
Disposes of sharps in a medical waste container without risk of needle sticks.		

Exiting the Cleanroom

Ensure that the cart or conveyance that is used to transport components of CSPs or materials from the Buffer areas do not cross the Line of Demarcation separating the "Clean" side of the anteroom from the "Dirty" side.		

Completed Preparations and Quality Control

Visually inspects finished preparations to ensure appearance is as expected, e.g., inappropriate visible particulates, foreign matters, discoloration, or other defects.		
Visually inspects finished preparations to ensure container-closure integrity such as leakage, cracks in the container, or improper seals.		
Performs other quality control checks appropriately per the Master Formulation record		
Labels preparations correctly.		
Performs final check of ingredients used against compounding record.		
Disposes of waste/sharps appropriately		

Evaluator Comments

Signature of Person Assessed Printed Name Date

Signature of Qualified Evaluator Printed Name Date

Attachment C: Sterile Training Documentation - Initial and Annual

Job Description: _____

Technician/Pharmacist: _____

General Training Requirements

Requirement	Date Completed	Employee Initials
Read and understand USP<797> and other applicable standards and relevant literature.		
Watch OSHA video on reading SDS		
Read and understand procedures related to compounding duties.		
Trained and understands how to interpret Safety Data Sheets (SDS) and if applicable, Certificates of Analysis.		
Trained and understands how to handle and transport of components and compounded sterile preparations		
Trained and understands how to perform pharmaceutical calculations relevant to their assigned duties		
Trained and understands the HD list, location of HD list, and how to access it		
Trained and understands location and use of eye washes and/or showers and spill kits		
Initial Training: Passes gloved fingertip and thumb sampling test 3 times with a CFU of 0.		
Subsequent Training: Passes a gloved fingertip and thumb sampling test after media fill testing with a CFU count ≤ 3		
Acceptably completes a hand hygiene and garbing practices observational assessment		

Employee Signature _____ Date: _____

Evaluator Signature: _____ Date: _____

Attachment D: Viable Air and Surface Testing

For Monthly Air and Surface Testing:

- Attach appropriate sample contact plates label and Certificate of Quality
- Document media serial number and expiration date
- Perform testing starting on site one and precede testing numerically per map ensuring testing is clean to less clean.
- Label with each plate the ID number and date tested.
- Once plates are sampled, place plates face down in a dedicated tote then transport from the sterile suite to tape the samples.
- Ensure the incubator is stabilized at 30°C to 35°C and it is equipped with a secondary temperature sensor. Where the incubators are tracked with alarms 24/7 a paper log is not necessary.
- Insert the plates in the Incubator face down for a minimum of 48 hours.
- Remove the plates carefully, inspect and note the results above.
- Replace samples to be incubated in house a second incubator set to maintain a range of 26°C to 30°C for 5 to 7 additional Days.
- Remove the plates carefully inspect & photo in such a way to clearly prove growth or no growth.
- When removed, the samples or clear photos of the samples shall be thoroughly inspected by Puritechsolutions, CETA number 00011047, who shall provide witness documentation.
- Samples showing growth shall be shipped via overnight delivery to US Micro to perform identification of the organism(s) genus and species. US Micro will provide a written report showing complete results of the identification testing and number of CFUs per sample.
    - The PIC is to be immediately notified if a sample is to be sent out to US Micro.
    - If the results require action, the Board of Pharmacy shall be immediately notified, and production shall be determined per their guidelines.

Attachment E:

SOP AND USP<797> ACKNOWLEDGEMENT

I _____ am stating that I have read and understand the non-sterile compounding standard operating procedures (SOP'S) and will abide by them. I also acknowledge I have read the current version of USP<797>.

By signing this form, I also understand that I could be randomly questioned on my understanding of the SOP'S and it is my responsibility to be familiar with and have a clear understanding of them, and how and where to access them. I understand that if I do not abide by the SOP'S that further training and review will be necessary. I have been provided with an opportunity to ask questions or clarify items related to this review. If I willfully and intentionally do not abide by the SOP'S set forth, management will take necessary disciplinary measures.

Employee Signature:_____ Date:_____

Witness Signature:_____ Date:_____

Title: Hazardous Drug Personnel Training **SOP # 9.003**
Version # 1.2
Written & Reviewed by: Connor Longo, PharmD. ***Date: 5/1/2024***
Authorized by: Christian Stella, PharmD. ***Date: 5/3/2024***

1) PURPOSE

a) To establish a training program in regards to identification and handling of hazardous drugs.

2) SCOPE

a) This SOP applies to all pharmacy personnel.

3) RESPONSIBILITY

a) The pharmacist in charge or their designee shall be responsible for implementation of this procedure.

4) REFERENCES

a) USP Current Version <800> "Hazardous Drugs –Handling in Healthcare Settings"

b) USP Current Version <795> "Pharmaceutical Compounding - Nonsterile Preparations"

5) DEFINITIONS

a) N/A

6) FREQUENCY

a) Personnel must receive training and competency assessments as required by this SOP prior to personnel independently working with hazardous drugs, whenever a change to the hazardous drugs list, and annually.

7) EQUIPMENT & SUPPLIES

a) N/A

8) GENERAL INFORMATION

a) The training in this procedure is based upon the particular employees' job description.

9) PROCEDURE

a) All personnel who handle or may be exposed to hazardous drugs shall complete and pass initial and annual training:

i) Training requirements:

(1) Read and understand SOP 9.002 Hazardous Communication Program

(2) Trainer will explain HD list, location of HD list, and how to access the HD list.

(3) Watch OSHA video on reading SDS: Watch SDS Video

(a) https://www.youtube.com/watch?v=vCI7XXExs7s

(4) Read and understand SOP 9.043 Accidental Exposure to Hazardous Drugs

(5) Read and understand SOP 9.015 Emergency Eye Wash

(6) Trainer will demonstrate location and use of eye washes and showers

ii) Competency Assessments:

(1) Complete and pass SOP 9.045 General Hazardous Drug Competency Test

b) All personnel required to wear PPE as part of their job duties:

i) Training requirements:

(1) Read and understand SOP 9.014 Respiratory protection

(2) Read and understand SOP 9.012: PPE For Sterile HD Compounding

(3) Read and understand SOP 9.013: Doffing PPE For Sterile HD Compounding

(4) Read and understand SOP 9.010: PPE For Non-Sterile HD Compounding

(5) Read and understand SOP 9.011: Doffing PPE For Non-Sterile HD Compounding

ii) Competency requirements:

(1) Complete and pass SOP 9.050: Sterile Hazardous Garbing Competency Test

(2) Complete and pass SOP 9.049: Non-Sterile Hazardous Garbing Competency Test

c) All personnel required to wear respiratory protection as part of their job duties:

i) Respiratory fit testing will be performed and documented.

d) All personnel which may have to handle HD spills:

i) Training requirements:

(1) Read and understand SOP 9.041 Cleaning Hazardous Drug Spills

(2) Read and understand SOP 9.042 Hazardous Drug Spill Kits

ii) Competency requirements:

(1) Complete and pass SOP 9.048 Hazardous Drug Spill Performance Audit

e) All personnel which receive HDs, package or ship HDs:

i) Training requirements:

(1) Read and understand SOP 9.016 Receiving Hazardous Drugs

(2) Read and understand SOP 9.017 Storage of Non-Sterile HDs and APIs

(3) Read and understand SOP 9.019 Packaging Hazardous Drugs for Dispensing

(4) Read and understand SOP 9.020 Shipping Hazardous Drugs

(5) Read and understand SOP 9.021 Transporting Hazardous Drugs

(6) Read and understand SOP 9.022 Labeling of HD Stock Containers

(7) Read and understand SOP 9.024 Finished and Exempt Dosage Forms

ii) Competency requirements:

(1) Complete and pass SOP 9.046 Hazardous Drug Compounding Competency Test

f) All personnel who work with engineering controls related to HDs:

i) Training requirements

(1) Read and understand: SOP 9.005 Monitoring Pressures of Sterile Hazardous Drug Compounding Areas

(2) Read and understand SOP 9.006 Monitoring Pressures of Non-Sterile Hazardous Drug Compounding Areas

(3) Read and understand SOP 9.007 Monitoring Pressures of Hazardous Drug Storage Areas

(4) Read and understand SOP 9.029 BSC Safety

ii) Competency requirements:

(1) Complete and pass SOP 9.045 General Hazardous Drug Competency Test

(2) Complete and pass SOP 9.046 Hazardous Drug Compounding Competency Test

(3) Complete and pass SOP 9.051 Engineering Control Competency Assessment

g) All personnel who compound HDs:

i) Training requirements:

(1) Read and understand SOP 9.025 Compounding techniques – Non-sterile Hazardous Drugs

(2) Read and understand SOP 9.026 Compounding techniques – Sterile Hazardous Drugs

(3) Read and understand SOP 9.027 HD Facilities for Non-HD Compounding

(4) Read and understand SOP 9.028 Transporting Hazardous Drugs Through a Non-hazardous Buffer Room (If applicable)

ii) Competency requirements

(1) Complete and pass SOP 9.045 General Hazardous Drug Competency Test

(2) Complete and pass SOP 9.046 Hazardous Drug Compounding Competency Test

(3) Complete and pass SOP 9.052 Non-Sterile HD Compounding Performance Audit

(4) Complete and pass SOP 9.053 Sterile HD Compounding Performance Audit

h) All personnel who receive HDs, compound with HDs or clean and maintain HD compounding facilities:

i) Training requirements:

(1) Read and understand SOP 9.031 Deactivating and Disinfecting Sterile Compounding BSCs

(2) Read and understand SOP 9.032 Deactivating and Disinfecting Sterile Compounding BSC Work Surfaces

(3) Read and understand SOP 9.034 Deactivating and Disinfecting Under Sterile Compounding BSC Work Surfaces

(4) Read and understand SOP 9.037 Deactivating and Disinfecting Sterile HD Compounding Areas

(5) Read and understand SOP 9.038 Deactivating and Cleaning of Non-Sterile BSCs

(6) Read and understand SOP 9.036 Deactivating and Cleaning Non-sterile HD Compounding Areas

(7) Read and understand SOP 9.039 Deactivating & Cleaning HD Receiving Areas

(8) Read and understand SOP 9.040 Deactivating and Cleaning HD Storage Areas

ii) Competency requirements:

(1) Complete and pass SOP 9.047 Deactivation and Decontamination Competency Test

(2) Complete and pass SOP 9.054 Deactivating and Disinfecting Sterile HD Compounding Areas Competency

(3) Complete and pass SOP 9.055 Deactivating and Disinfecting Non-Sterile HD Compounding Areas Competency

i) Upon completion of the above, all personnel are required to take and pass the Hazardous Drugs Exam, found in SOP 9.056, acknowledge Hazard communication and employee training document in SOP 9.002, and to sign the FM-11 Hazardous Drug Handling and Exposure Acknowledgement, to confirm and document their understanding.

10) ATTACHMENTS

a) N/A

Title: Telehealth Company Drug Shipping **SOP #12.001**
Version #1.0
Written & Reviewed by: Connor Longo, PharmD. ***Date: 7/1/24***
Authorized by: Christian Stella, PharmD. ***Date: 7/1/24***

1) PURPOSE

a) To ensure that medications are delivered to the patient or health care facility quickly and in a manner, such that the product integrity, quality, safety, and efficacy are not compromised.

b) To ensure timeliness of shipping prior to administration date

c) Ability to track shipping/delivery

d) Plans to notify patient of shipping delays

e) Processes are in place to ensure continuous supply of medication if package is lost or delayed

2) SCOPE

a) This procedure applies to all employees involved in the shipping and delivery of medication.

3) RESPONSIBILITY

a) The Pharmacist-in-charge or their designee will be responsible for implementation of this procedure.

4) REFERENCES

a) USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

b) Applicable Board of Pharmacy rules and regulations

c) Data/literature regarding stability and storage requirements for the particular product(s) being shipped

5) DEFINITIONS

a) N/A

6) FREQUENCY

a) This procedure shall be followed for each prescription filled for shipment

7) EQUIPMENT & SUPPLIES

a) Compounded preparation(s) and appropriate equipment/devices if necessary

b) Appropriate medication container and label

c) Delivery vehicle, detailed delivery instructions

d) Appropriate shipping containers, ice packs and methods to ensure integrity

e) Signature log sheet or electronic log

f) Shipping tracking instructions

8) GENERAL INFORMATION

a) N/A

9) PROCEDURE

a) The responsible personnel shall assure that the compounded preparation is properly delivered to the patient or health care facility without compromising the product integrity, quality, safety and efficacy.

b) All medications shall be delivered/shipped in appropriate containers that will protect the preparation from wide variations in temperatures, structural damage, or UV light when appropriate.

c) Before any medication for shipping, delivery, or pick up is packaged it is to be checked by a pharmacist to ensure that the right medication is in there (via checking batch/lot numbers for compounding medications), ensure that the quantity is correct, it is for the right patient, contains appropriate informational handouts, that it is going to the correct address, and if the shipment will be going out with overnight shipping if it is requested.

d) For telehealth companies that provide prescriptions for controlled substances of any schedule, the telehealth company provides the pharmacy with their specific requirements when it comes to the option of "signature required" upon shipping.

a) If the telehealth company requires that "signature required" is to be on all of their prescriptions, then the pharmacist checking the prescription will ensure that "signature required" is on all shipping labels for that telehealth company.

b) Controlled substances of any schedule are to be packaged in a way to make the package inconspicuous to prevent diversion as well as having a tamper evident seal. In the case of a troche or rapidly dissolving tablet, they are to be placed inside a child resistant bag prior to being sent out.

c) When checking prescriptions, the pharmacist is to toss the unused portion of the prescription label and dispose of it in a HIPPA compliant bin. This bin is outsourced for shredding and proper disposal in a HIPPA compliant manner.

e) All medications that are being shipped and delivered will have a tracking number attached to the prescriptions electronic page to reference at any time. The tracking numbers will be active on the appropriate third-party website for shipping i.e. FedEx or USPS.

f) Shipping into some states requires special temperature monitoring devices. When required, these will be included in the appropriate packages.

g) The patient or authorized recipient signature shall be recorded on the delivery receipt when the product is delivered, and a copy shall be left with the recipient. (Signature required packages will be sent through UPS only and will NOT be delivered locally)

a) Some patients may prefer to have their packages left at the door or some other location on the premises. In this case the driver will make a notation on the delivery log.

b) When medications are left at the door or other location on the premises, the driver must be cognizant that the medication is relatively secure and not subject to harmful temperatures.

h) The local driver shall check the package for any leakage or damage that may occur during delivery.

i) Instructions for proper inspection of the preparation will be transmitted to the patient or caregiver prior to delivery of the package.

j) When shipping medications and related devices, a packing slip and or receipt listing the contents, charges, and payment type shall be included in the shipping container.

a) Drugs, which must remain at cold temperatures will be shipped in insulated containers with the number/size of cold packs recommended by the vendor or verified in shipping tests performed by the pharmacy.

(1) The winter packing method was determined based on cold chain shipment testing that occurred on March 27, 2024, in which 1 shipment was sent per state to (3 total shipments) Minnesota, Maine, and Idaho. These tests were performed with 2x12oz Frozen ice packs, and 2x6oz ambient ice packs in a metallic mailer. Testing yielded results between 0 and 8 degrees Celcius from 31.5 hours to 46 hours.

b) Utilize time-temperature indicators, both warm and cold, in the package to ensure that the storage conditions have been met throughout the shipment route, when required.

(1) When packages are shipped with temperature monitoring devices written instructions regarding the temperature monitoring device will be included in the package.

(2) Follow up with the receiver to ensure that the package arrived in good condition and within acceptable storage conditions range.

(a) In the event that the shipment was exposed to temperature excursions, the indicator will signal such to the customer, which will render the product as unusable.

c) The shipping log/shipping documentation from USPS, USP, FedEx shall serve as the patient signature and receipt of shipment.

d) Shipping medications in the summer/winter may create special shipping problems. The responsible person should determine if heat or freezing can harm the contents of the shipment.

(1) If so, shipping may require alternate packaging methods (warm packs, ice packs, insulated packaging, etc.).

e) The responsible person should proactively identify weather conditions that may lead to a possible delay by referencing UPS, FedEx, and/or Weather.com.

k) Storage instructions shall be provided to the patient or caregiver to ensure that the product is stored appropriately at the patient's home or at the health care facility. Patients will be reminded not to leave their medication in their car during hot or cold months.

l) In the event of a shipping delay

a) The patient can expect the medication to arrive on time and undamaged. When shipping problems occur due to inclement weather or other natural disaster, the PIC will make every effort to arrange either a second delivery or transfer of the prescription to a pharmacy nearer the patient or to an area unaffected by the weather.

b) The PIC will contact the prescriber and discuss medication therapy management and what problems, if any, the delay in shipping may cause the patient.

(1) If the medication is of a serious nature such as HIV therapy, acute illness or similar, the PIC will make arrangements to have the medication delivered to the patient as soon as possible, including necessary interim doses, via the fastest method, including having the prescription filled at the patient's local pharmacy of choice.

(2) The PIC will follow up with the patient and prescriber and document in the patient's medication record

m) During times of inclement weather, holiday shipping, or pharmacy dispensing problems the patient will be contacted to discuss the potential for a delay.

n) Communications regarding delays will be noted in the patient chart

o) **Lost, Stolen, Delayed, or Diverted Shipments**

a) If it is brought to an employee's attention that a shipment or delivery is lost or delayed the following is to occur;

(1) The tracking number is to be referred to ensure that this is the case

(2) Once confirmed the third party involved is to be contacted and an investigation into the package's whereabouts is to be conducted

(3) If the third party deems the package lost, a claim is to be filed for the lost package

(a) In this instance, the medication is to be remade and sent to the patient

(b) In the case of a controlled substance, the prescribing physician is to be contacted to explain what happened and to receive a new, valid prescription for the medication

(4) If the third-party deems the package is delayed and will be arriving to the patient soon, the patient is to be informed

(5) If the third-party deems that the package is delayed and cannot give a timeframe of when it will reach the patient, the package is to be rerouted to be returned to the pharmacy while a replacement medication is sent to the patient immediately.

(a) In the case of a controlled substance, the pharmacist is to contact the prescribing physician to explain what happened and to receive a new, valid prescription for the medication

b) If it is brought to an employee's attention that a shipment or delivery has been stolen, a police report is to be filed immediately. The report is to be maintained for the pharmacy's records. Once the police report deeming the theft has been obtained, the medication is to be remade and resent to the patient with "signature required"

(1) In the case of a controlled substance, a DEA Form 106 is to be filed as well. A pharmacist is then to contact the prescribing physician to explain what happened and to receive a new, valid prescription for the medication.

p) Returned Medications

a) If a patient wishes to return a medication, they are to be provided with a return label generated via the third party's website that can be mailed or faxed to their home, and documented in the pharmacy software.

(1) In the case of a controlled substance, the return needs to meet the requirements set forth in the DEA Pharmacist's Manual;

(a) the inner container of any parcel containing controlled substances is marked and sealed as required by the provisions of the CSA and its implementing regulations, and is placed in a plain outer container or securely wrapped in plain paper

(b) If the controlled substance consists of prescription medicines, the inner container is also labeled to show the name and address of the pharmacy, practitioner, or other person dispensing the prescription

(c) The outside wrapper or container is free of markings that would indicate the nature of the contents

b) If a medication is returned, the store manager is to obtain the packages and quarantine all drugs as they are no longer suitable for dispensing once they leave the pharmacy even if they are seemingly untouched, as per New York State law. The patient's prescription record is to reflect the return of medication and the prescription is to be reversed.

(1) Returned items are to be properly inventoried to ensure all that was returned has been removed and destroyed. when placed into inventory, all PHI is to be removed from the drugs/devices. The original inventory record is to be maintained on site. Once given to the reverse distributor, the inventory is to be promptly updated.

(2) The Pharmacy will use a third-party reverse distributor to destroy all returned medications and devices.

(a) The reverse distributor used by the pharmacy must be an authorized reverse distributor. The store manager is to ensure this by verifying the reverse distributors' state and federal licenses prior to using them. Records of this are to be maintained and verified quarterly.

(b) Prior to the drugs/devices being given to the reverse distributor, the store manager is to check that all PHI is to be removed from the drugs/devices, which should have been completed prior to going into inventory.

(c) The pharmacy is to provide the reverse distributor with a copy of the inventory record.

(d) The reverse distributor is to send the pharmacy a certificate of destruction, which the pharmacy will maintain for its records.

(i) The certificate of destruction should state the means of destruction and she be provided to the pharmacy no more than three months from the shipment of the return to them

(ii) The store manager is to keep an inventory log and calendar of all items sent to the reverse distributor and monitor that the certificate of destruction has been received. If it has not, the store manager must request the certificate of destruction from the reverse distributor.

Preferably this is to be done two weeks prior to the three-month end date to allow time to receive the certificate before the three months have passed.

10) ATTACHMENTS

a) Orientation Checklist – Delivery Liaison

b) Packing Instructions

Attachment A Orientation Checklist – Delivery Liaison

Attachment: ORIENTATION CHECKLIST – DELIVERY LIAISON

NAME: _____

Date	Departments/ Procedures Reviewed	Materials/References Used	Initials of Employee	Initials of Dept. Rep.
	Shipping/receiving			
	Trash/dumpster			
	Dispensing area			
	Delivery vehicle parking			
	Delivery logs			

Signature: _____ *Date:* _____
Supervisor

Signature: _____ *Date:* _____
Team member

Packing Instructions:

Packing Cold or Frozen Items:

- The item goes into either a insulated box or insulated sac
- The box or sac is then packed with ice packs stored in the freezer dedicated for shipping ice packs along with the item as well as any required additional items
    - o i.e an applicator, oral syringes, dedicated instructional sheets, patient information sheets
- The box or sac is appropriately sealed with tape
- The shipping label is affixed to the box or sac
- A international sa fe handling label, "Refrigerate Do Not Freeze," is affixed to the box or sac
- All cold or frozen items are not taken out of the refrigerator/ freezer until the end of the day to ensure that it experiences the least amount of time out of the refrigerator/freezer
- Once removed from the refrigerator/freezer these items are to be packed ASAP to ensure they maintain their required temperature

Packing Normal Temperature Items:

- The item goes into either a box or a bubble mailer
- The box or bubble mailer is then packed with the item as well as any required additional items
    - o i.e an applicator, oral syringes, dedicated instructional sheets, patient information sheets
- The box or bubble mailer is appropriately sealed with tape
- The shipping label is affixed to the box or bubble mailer

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Precision Compounding Pharmacy and Wellness

Pharmacy/Wholesaler License # (if applicable): PH 04486

Physical Address: 2657 Merrick Rd

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-833-6262 Website: mypcphealth.com

Licensing Company Email: licensingNY@mypcphealth.com

Section 2: Personal Information

First: Jeriann Middle: Last: Stella

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Merrick State: NY Zip: 11566

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St Johns University		09/95 - 05/01	
Address	**City**	**State**	**Zip**
8000 PKWY.	Jamaica	NY	11439
Diploma/Degree obtained, if any			
Batchelor/Pharmacy.			
School Name		**From - To (MM/YY – MM/YY)**	
South Shore High School		09/91 - 06/95	
Address	**City**	**State**	**Zip**
6565 Flatlands Ave.	BKLYN	NY	11236
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/20 - Current	[redacted]	Merrick	NY	11566
8/06 - 12/20	[redacted]	Merrick	NY	11566
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
Precision Compounding.		9/21 – current
Business Address	**City**	**State / Zip**
2657 Merrick Rd.	Bellmore	NY 11710.
Phone	**Title**	**Number of Employed Hours**
516 8338262	Pharmacist	20,000.

Description of Duties

Staff pharmacist /

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Great Neck Chemist		09/01-07/14
Business Address	**City**	**State / Zip**
665 Middle Neck Road	Great Neck	NY 11024
Phone	**Title**	**Number of Employed Hours**
5164820004.	Staff pharmacist	18,720.

Description of Duties

Staff pharmacist

Business Name		From - To (MM/YY – MM/YY)
Stella Pharmacy		09/01-1/07)
Business Address	**City**	**State / Zip**
8722 Glenwood Road.	Brooklyn	NY 11236
Phone	**Title**	**Number of Employed Hours**
(718)2728410.	Pharmacist.	6,000.

Description of Duties

Staff Pharmacist

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jeriann Stella, **certify that as the designated representative for**

Precision Compounding Pharmacy and Wellness,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeriann Stella

Print Name (First, Last)

Original Signature ~~(electronic copies or stamps not accepted)~~

8/1/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeriann Stella

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Jeriann Stella, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/1/24

Date

Subscribed and Sworn to before me this 1st day of August.

Notary Public Signature

LINDA IMERTI
Notary Public, State of New York
No. 01IM5213669
Qualified in Nassau County
Commission Expires Nov. 9, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Precision Compounding Pharmacy and Wellness

Pharmacy/MDEG/Wholesaler License # (if applicable): PH04486

Physical Address: 2657 Merrick Road

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-833-6262 Website: mypcphealth.com

Licensing Company Email: licensingny@mypcphealth.com

Section 2: Personal Information

First: Christian Middle: Frank Last: Stella

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Merrick State: NY Zip: 11566

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/2010-06/2016	
Address	**City**	**State**	**Zip**
8000 Utopia Parkway	Jamaica	NY	11432
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
John F. Kennedy High School		09/2006-06/2010	
Address	**City**	**State**	**Zip**
3000 Bellmore Ave	Bellmore	NY	11710
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2021-Present	[redacted]	Merrick	NY	11566
From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/1992-03/2021	[redacted]	Merrick	NY	11566
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Precision Compounding Pharmacy and Wellness			01/2017-Current
Business Address	**City**	**State**	**Zip**
2657 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-833-6262	Pharmacist-in-Charge/Owner/CEO		
Description of Duties			
Preformed the duties of a Pharmacist-in-Charge as well as operated as a staff pharmacist, until he became an owner on 8/1/2024			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christian Frank Stella

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Christian Stella, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/1/2024

Date

Subscribed and Sworn to before me this 1st day of August.

Notary Public Signature

LINDA IMERTI
Notary Public, State of New York
No. 01IM6213569
Qualified in Nassau County
Commission Expires Nov. 9, 2021

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Precision Compounding Pharmacy and Wellness

Pharmacy/MDEG/Wholesaler License # (if applicable): PH04486

Physical Address: 2657 Merrick Rd

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-833-6262 Website: mypcphealth.com

Licensing Company Email: licensingny@mypcphealth.com

Section 2: Personal Information

First: Frank Middle: Last: Stella

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City: Merrick State: NY Zip: 11566

Telephone [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Xaverian High School		09/1992-06/1996	
Address	**City**	**State**	**Zip**
7100 Shore Rd	Brooklyn	NY	11209
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/1996-05/2001	
Address	**City**	**State**	**Zip**
8000 Utopia Parkway	Jamaica	NY	11439
Diploma/Degree obtained, if any			
Bachelor's of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2006-12/2000	[redacted]	Merrick	NY	11566
11/2000-Current	[redacted]	Merrick	NY	11566

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Belle Harbor Chemists			01/2000-Present
Business Address	**City**	**State**	**Zip**
449 Beach 129th St	Belle Habro	NY	11694
Phone	**Title**		
718-634-0001	Owner/PIC		
Description of Duties			
Preformed the duties of an owner, pharmacist-in-charge, and a staff pharmacists			

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Bellmore			03/2009-Present
Business Address	**City**	**State**	**Zip**
2640 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-785-4774	Owner		
Description of Duties			
Preformed the duties of an owner and staff pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Precision Compounding Pharmacy and Wellness			11/2021-Present
Business Address	**City**	**State**	**Zip**
2657 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-833-6262	Owner		
Description of Duties			
Preformed the duties of an owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Frank Stella

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Frank Stella, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/1/24

Date

Subscribed and Sworn to before me this 1st day of August.

Notary Public Signature

LINDA IMERTI
Notary Public, State of New York
No. 01IM6213569
Qualified in Nassau County
Commission Expires Nov. 9, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Precision Compounding Pharmacy and Wellness

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04486

Physical Address: 2657 Merrick Road

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: 516-833-6262 Website: mypcphealth.com

Licensing Company Email: licensingny@mypcphealth.com

Section 2: Personal Information

First: Richard Middle: Last: Longo

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Garden City State: NY Zip: 11530

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nazareth Regional High School		09/1985-06/1989	
Address	**City**	**State**	**Zip**
475 E 57th St	Brooklyn	NY	11203
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/1989-05/1994	
Address	**City**	**State**	**Zip**
8000 Utopia Parkway	Jamaica	NY	11439
Diploma/Degree obtained, if any			
Bachelor's of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/1999-Current	[redacted]	Garden City	NY	11530
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Belle Harbor Chemists			04/1997-Present
Business Address	**City**	**State**	**Zip**
449 Beach 129th St	Belle Habro	NY	11694
Phone	**Title**		
718-634-0001	Owner		
Description of Duties			
Preformed the duties of an owner and a staff pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Bellmore			03/2009-Present
Business Address	**City**	**State**	**Zip**
2640 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-785-4774	Owner/PIC		
Description of Duties			
Preformed the duties of an owner, pharmacist-in-charge, and staff pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Precision Compounding Pharmacy and Wellness			11/2021-Present
Business Address	**City**	**State**	**Zip**
2657 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-833-6262	Owner		
Description of Duties			
Preformed the duties of an owner			

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Great Neck			08/2018-Present
Business Address	**City**	**State**	**Zip**
665 Middle Neck Rd	Great Neck	NY	11023
Phone	**Title**		
516-482-0005	Owner		
Description of Duties			
Preformed the duties of an owner			

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Long Beach			02/2013-Present
Business Address	**City**	**State**	**Zip**
629 E Park Ave	Long Beach	NY	11561
Phone	**Title**		
516-889-8899	Owner		
Description of Duties			
Preformed the duties of an owner			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Longo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Richard Longo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/1/24

Date

Subscribed and Sworn to before me this 1st day of August.

Notary Public Signature

LINDA IMERTI
Notary Public, State of New York
No. 01IM6213569
Qualified in Nassau County
Commission Expires Nov. 9, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Precision Compounding Pharmacy and Wellness

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04486

Physical Address: 2657 Merrick Road

City: Bellmore State: NY Zip: 11710

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-833-6262 Website: mypcphealth.com

Licensing Company Email: licensingny@mypcphealth.com

Section 2: Personal Information

First: Frank Middle: Last: Longo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bellmore State: NY Zip: 11710

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nazareth Regional High School		09/1978-06/1982	
Address	**City**	**State**	**Zip**
475 E 57th St	Brooklyn	NY	11203
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/1982-05/1987	
Address	**City**	**State**	**Zip**
8000 Utopia Parkway	Jamaica	NY	11439
Diploma/Degree obtained, if any			
Bachelor's of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2000-Current	[redacted]	Bellmore	NY	11710
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Belle Harbor Chemists			07/1997-Present
Business Address	**City**	**State**	**Zip**
449 Beach 129th St	Belle Harbor	NY	11694
Phone	**Title**		
718-634-0001	Owner		

Description of Duties
Preformed the duties of an owner and a staff pharmacist

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Bellmore			07/2009-Present
Business Address	**City**	**State**	**Zip**
2640 Merrick Rd	Bellmore	NY	11710
Phone	**Title**		
516-785-4774	Owner/PIC		

Description of Duties
Preformed the duties of an owner, pharmacist-in-charrge, and staff pharmacist

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Great Neck			08/2018-Present
Business Address	**City**	**State**	**Zip**
665 Middle Neck Rd	Great Neck	NY	11023
Phone	**Title**		
516-482-0005	Owner		

Description of Duties
Preformed the duties of an owner

Business Name			From - To (MM/YY – MM/YY)
Precision Pharmacy of Long Beach			12/2013-Present
Business Address	**City**	**State**	**Zip**
629 E Park Ave	Long Beach	NY	11561
Phone	**Title**		
516-889-8899	Owner		

Description of Duties
Preformed the duties of an owner

Business Name			From - To (MM/YY – MM/YY)
Great Neck Chemists Inc. of NY			09/1987-Present
Business Address	**City**	**State**	**Zip**
69 Allen Blvd	Farmingdale	NY	11735
Phone	**Title**		
516-466-7700	Owner		

Description of Duties
Preformed the duties of an owner

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Precision Compounding Pharmacy and Wellness			11/2021-Present	
Business Address		**City**	**State**	**Zip**
2657 Merrick Road		Bellmore	NY	11710
Phone	**Title**			
516-833-6262	Owner			
Description of Duties				
Preformed the duties of an owner				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Frank Longo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 8/1/24

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Frank Longo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 8/1/24

Subscribed and Sworn to before me this 1st day of August.

Notary Public Signature

LINDA IMERTI
Notary Public, State of New York
No. 01IM6213569
Qualified in Nassau County
Commission Expires Nov 9, 2025

(Seal)

PI Plan of Correction Form

Threshold:
Actual Result:

PI Program Annual Summary

1. Effectiveness, quality and appropriateness of care/service provided to clients/patients.
2. Effectiveness of the overall administration and fiscal operations.
3. Effectiveness of all programs including care/service provided under contractual arrangements.
4. Utilization of personnel.
5. Review and revision of policies and procedures and forms used by the organization.
6. Review of annual PI report.

Prepared by: _____ Date: _____

nit Dose Label Options

Enable Unit Dose Labels

Template: 1" x 2.625"

Description: NAD+ (5mL vial)

Subtitle: 200mg/mL

Product Usage/Details: This is a compounded preparation. Discard after 28 days of puncturing. This is a multidose vial.

Usage Instructions: Clear and pale yellow to colorless solution

Storage Instructions: Refrigerate upon opening /
Protect from light

Table 4. BUD Limit by Type of Preparation in the Absence of a *USP–NF* Compounded Preparation Monograph or CNSP-Specific Stability Information[a]

Type of Preparation	BUD (days)	Storage Temperature[b]
Aqueous Dosage Forms ($a_w \geq 0.60$)		
served aqueous dosage forms[c]	14	Refrigerator
ed aqueous dosage forms[c]	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
uids (nonaqueous)[d]	90	Controlled room temperature or refrigerator
onaqueous dosage forms[e]	180	Controlled room temperature or refrigerator

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1642365		**Inspection Information**
Legal Business Name:	Precision Compounding Pharmacy & Wellness Inc.	**Conference Call Date:**	5/29/2024
Doing Business As (DBA):	Precision Compounding Pharmacy	**Start Time: 24-hour format (13:00)**	9:00
Address:	2657 Merrick Road	**End Time: 24-hour format (13:00)**	10:59
City:	Bellmore	**Onsite Inspection Date(s):**	5/30/2024
State:	New York	**Start Time(s): 24-hour format (13:00)**	8:15
Zip Code:	11710	**End Time(s): 24-hour format (13:00)**	16:20
Telephone number:	516-833-6262	**Inspector Name(s):**	Howard Kramer RPh
Toll free number:	855-535-8333	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	516-222-0605	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.mypcphealth.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 51.00, 83.00, 84.00, 87.02, 91.00 and 93.00

Nonsterile - 28.0 and 28.7

Sterile- 12.0, 12.12, 31.0, 31.2, 58.0, 58.5, 71.0 and 71.11

Additional information on NABP's Inspection website

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party..

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	17:00	
Tuesday	9:00	17:00	
Wednesday	9:00	17:00	
Thursday	9:00	17:00	
Friday	9:00	17:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Christian Stella	cstella@mypcphealth.com	1195027
Nonsterile Designated person(s)	Kevin Von Bargen	kvonbargen@mypcphealth.com	1473582
Sterile Designated person(s)	Lisa Capriola	lcapriola@mypcphealth.com	1466680
Hazardous Designated person(s)	Lisa Capriola	lcapriola@mypcphealth.com	1466680

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Christian Stella	PIC	Y
2	Lisa Capriola	VP of Compliance, Pharmacist	Y
3	Elizabeth Mortillaro	Sterile Pharmacist	Y
4	Kevin Von Bargen	Non-sterile Pharmacist/Clinical Director	Y
5	Stephen Davis	Non-sterile Pharmacist	Y
6	Maryam Khan	Pharmacist	Y
7	Larissa Norris	Pharmacist	Y
8	Jake Reikert	Pharmacist	Y
9	Nora Gonzalez	Non-sterile Compounding Technician	Y
10	Christina Pinzone	Non-sterile Compounding Technician	Y

There were two technicians in addition to the above.

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
New York State Board of Pharmacy	Precision Compounding Pharmacy and Wellness	Pharmacy	39041 Exp: 10/31/2024
Drug Enforcement Administration	Precision Compounding Pharmacy and Wellness	Controlled Substance - Pharmacy	FP0999637 Exp: 3/31/2027

Inspector Notes: Non-resident licenses are held in AK, AZ, CA (NS only), CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI, and WY. This pharmacy compounds non-sterile, non-sterile hazardous and non-hazardous sterile products in multidose vials and ships via UPS and USPS to the states noted above and within NY. The pharmacy ceased sterile hazardous compounding approximately 8 weeks ago, and has no plans to resume at this time. While the pharmacy does not participate in primary telepharmacy, prescriptions filled may be provided by patients and prescribers participating in telemedicine processes. Please see Doc01_PI for a list of telepharmacy partners which include the following: Advitam, Better U Care, CHOOSE KETAMINE, Innerwell, Journey Clinical, Mindbloom, VikingMan, Aspect, Wittmer Rejuvenation Clinic, Brittany Kelly NP Family Health PLLC, Corrective Wellness, Dynamic Health Solutions, Evolved Science, Ketadash/Synergy Health, Moment Health, TCT, Algo, Bask Health, BMI MD, EDEN, IvyRX, AgelessRX, Huge Rx, Matrix Hormones, SAFERPHARM, VeriNew, Weight Loss Ventures(Kinlife), LLC, EVVY, Hone Health, LifeForce, Male MD, Midi, WISP, and Maximus Tribe. The due diligence for the pharmacy includes using BulaLaw to verify state laws related to telepharmacy and Verifiable to review the license status of all providers on a monthly basis. All telemedicine companies are required to complete an account set-up form which includes a list of all providers to be reviewed, their license information, and the telemedicine compliance structure which is vetted including all investors in the company. The PIC stated they have only a 20% acceptance rate for telemedicine companies applying for partnership. A Zoom call is also required for account set-up. Please see Doc02_PI for the due diligence requirements for telehealth companies, Approximately 50% of the ketamine and testosterone prescriptions are from the telemedicine partners. The balance is from NY and NJ prescribers. Prescriber notes may be sent by the prescriber or may be requested by the pharmacy. Sildenafil accounts for approximately 2% of the pharmacy prescription volume, with the major use as a component in vaginal creams. The major use of testosterone is in non-sterile compounding as a component with estriol and estradiol. PharmSaver is not currently used and has not been a source of supply for 18 to 24 months. The only WD used is McKesson. All APIs are purchased from major manufacturers and repackagers as noted in the report. Assessing and trending QREs takes place during the quarterly CQI review. There is no insulin stocked and there was no ReliOn insulin observed. There are no biologicals compounded. Semaglutide is compounded using semaglutide base. Please see Doc03_PI for the MFR, CR, and CoA for a semaglutide compound (SeePhoto01_PI and Photo02_PI for photos of semaglutide base package label). The PIC stated there are no platforms used that are a marketplace for pharmacies to buy, sell and bid on overstock and short date prescription drugs.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_PI; Doc02_PI; Doc03_PI	List of telemedicine partners; Due diligence requirements for vetting telemedicine partners; MFR, CR and COA for semaglutide compound
Doc04_NS_29.0; Doc05_ST_50.3	Sample of NS MFR and CR compound; List of API suppliers
Doc06_Haz_1.01; Doc07_Haz_3.00	Hazardous drug APIs handled; Items handled on the current NIOSH list
Photo01_PI; Photo02_PI	Photos of semaglutide base package label
Photo03_ST_12.12: Photo04_ST_12.12	Photos of bench used as line of demarcation

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	X
Telepharmacy		Sterile Compounding	X
Internet Pharmacy	X	Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)	X	CSPs with controlled substance(s)	X
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	X
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations	X	Immediate Use	
Vaginal preparations	X	Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:	X	Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	4000	Total Pharmacists:	11
Nonsterile Compounding Room size:	850	Number of Compounding Pharmacists:	4
Nonsterile Compounding powder hoods number:	8	Total Student Interns:	1
Nonsterile Hazardous Drugs (HD) Compounding Room size:	850	Total Technicians:	12
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	6	Number of Compounding Technicians:	9
Sterile Compounding Ante Room size:	400	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	400	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	2/10 each	Total Other Unlicensed Personnel:	4
Sterile Compounding Number BSC hoods:	1	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	6 techs: 10 RP
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	400		
Sterile HD Compounding Number of BSC hoods:	1		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	The inspector garbed and entered to anteroom where full observation of compounding was adequate.

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	1500	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	5%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	30%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	70%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	15%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	29	0	week (4/21/24-4/27/2024)
Arizona (AZ)	315	0	week (4/21/24-4/27/2024)
Arkansas (AR)			
California (CA)			
Colorado (CO)	272	0	week (4/21/24-4/27/2024)
Connecticut (CT)	136	0	week (4/21/24-4/27/2024)
Delaware (DE)	29	0	week (4/21/24-4/27/2024)
District of Columbia (DC)	51	0	week (4/21/24-4/27/2024)
Florida (FL)	882	0	week (4/21/24-4/27/2024)
Georgia (GA)	517	0	week (4/21/24-4/27/2024)
Hawaii (HI)	56	0	week (4/21/24-4/27/2024)
Idaho (ID)	70	0	week (4/21/24-4/27/2024)
Illinois (IL)	333	0	week (4/21/24-4/27/2024)
Indiana (IN)	162	0	week (4/21/24-4/27/2024)
Iowa (IA)	107	0	week (4/21/24-4/27/2024)
Kansas (KS)	59	0	week (4/21/24-4/27/2024)
Kentucky (KY)			
Louisiana (LA)	64	0	week (4/21/24-4/27/2024)
Maine (ME)	73	0	week (4/21/24-4/27/2024)
Maryland (MD)	274	0	week (4/21/24-4/27/2024)
Massachusetts (MA)	380	0	week (4/21/24-4/27/2024)
Michigan (MI)	359	0	week (4/21/24-4/27/2024)
Minnesota (MN)	234	0	week (4/21/24-4/27/2024)
Mississippi (MS)	1	0	week (4/21/24-4/27/2024)
Missouri (MO)	220	0	week (4/21/24-4/27/2024)
Montana (MT)	56	0	week (4/21/24-4/27/2024)

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	47	0	week (4/21/24-4/27/2024)
Nevada (NV)	230	0	week (4/21/24-4/27/2024)
New Hampshire (NH)	43	0	week (4/21/24-4/27/2024)
New Jersey (NJ)	391	0	week (4/21/24-4/27/2024)
New Mexico (NM)	66	0	week (4/21/24-4/27/2024)
New York (NY)	1192	0	week (4/21/24-4/27/2024)
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)	360	0	week (4/21/24-4/27/2024)
Oklahoma (OK)	93	0	week (4/21/24-4/27/2024)
Oregon (OR)	229	0	week (4/21/24-4/27/2024)
Pennsylvania (PA)	397	0	week (4/21/24-4/27/2024)
Rhode Island (RI)	39	0	week (4/21/24-4/27/2024)
South Carolina (SC)			
South Dakota (SD)	25	0	week (4/21/24-4/27/2024)
Tennessee (TN)	271	0	week (4/21/24-4/27/2024)
Texas (TX)	1543	0	week (4/21/24-4/27/2024)
Utah (UT)	180	0	week (4/21/24-4/27/2024)
Vermont (VT)	12	0	week (4/21/24-4/27/2024)
Virginia (VA)	484	0	week (4/21/24-4/27/2024)
Washington (WA)	389	0	week (4/21/24-4/27/2024)
West Virginia (WV)	43	0	week (4/21/24-4/27/2024)
Wisconsin (WI)	168	0	week (4/21/24-4/27/2024)
Wyoming (WY)	19	0	week (4/21/24-4/27/2024)
Other:			

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General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	The PIC is onsite approximately 45 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	Yes	Vetmedics Compounding Pharmacy in Ronkonkoma, NY and Precision Compounding Pharmacy (South) in Tamarack, FL are affiliates which link to the website.
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	Refill requests may be submitted by completing a form using the prescription number.
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Christian Stella and Lisa Capriola were interviewed.

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e-Profile ID: 1642365
Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
Types of Practice Additional Questions	**If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The last inspection report by NY was dated 3/27/2024. There appear to be no scheduled inspections in NY.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	The HD buffer room was not negative pressure at the time of the inspection. The room was deactivated and has not been used since that time. HVAC, the environmental certification company, came in and adjusted the airflow, however, the room has not been used since the inspection and will likely be converted into a non-hazardous sterile compounding buffer room.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	NABP Compounding Pharmacy Accredited
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained for 5 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	These records are maintained electronically for 5 years or more.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	These records are maintained electronically for 5 years or more.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	These records are maintained electronically for 5 years or more.

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is part of P & P.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	This is documented in a spreadsheet with the date issued, and the license expiration dates. A physical copy of each license is printed from the primary source verification website and maintained in the personnel file.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Primary source verification is completed annually and documented in the personnel record.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The NY maximum technician ratio is 3:1. The maximum number working at any time in this pharmacy is 10 technicians and 6 pharmacists.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The security system is managed by Century and consists of magnetic door sensors and motion detections devices. A skylight in the NS area has a glass break sensor. The front door is a hard key lock. The back door requires a hard key and an electronic key fob. A keypad arms and disarms the system. Three pharmacists have a unique PIN to disarm the system. Alarms are sent to the PIC by text, phone call and email. Notifications go to the other two pharmacists and a another shareholder if there is no response from the PIC.

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Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy
e-Profile ID: 1642365
Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	CII drugs (only testosterone, a CII drug in NY) are in a locked cabinet available only to the supervising pharmacist (PIC).
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Local police are contacted and a pharmacist would stay on site until security is restored or until drugs can be relocated to one of the affiliate pharmacies.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	There are no drugs destroyed onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	The reverse distributor is Cyntox LLC in NY, NY.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Cyntox picks up hazardous waste on an on-call basis.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The patient lobby is sectioned off with privacy panels for counseling.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The temperature is thermostatically controlled by staff. The current temperature is 68 degrees F.

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	A HOBO system electronically monitors and records the CRT area temperature.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Product is quarantined and sent out for testing if integrity is questionable.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	There is no frozen product.
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	SensoScientific electronically monitors and records the temperatures in the refrigerators. The range is 36 to 46 degrees F. Excursions are sent to the VP of Compliance by a phone app. Records are maintained infinitely.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	The refrigerator temperatures are currently 37.4, 37.6, 36.1, 41.5, and 39.4 degrees F.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There is an onsite portable generator which will power the entire building. There are multiple refrigerators allowing product to be moved to a working appliance.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	There are multiple heating and air-conditioning units which can handle HVAC for the entire facility. Cambridge AC located in Bensonhurst, NY is on call for emergencies.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	

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		Observation	Notes
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

Product Receipt and Inventory

If any part of a question is no, enter "No" and explain the observation.

47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	All vendors must be properly licensed in their home state and New York. State and federal inspections for the vendor are reviewed.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	McKesson, an NABP accredited wholesaler, is the single source of prescription drugs.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	The single source of prescription drugs is McKesson, an NABP accredited wholesaler. There is no verification of all McKesson purchases from the manufacturer.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	DSCSA drugs are purchased only from McKesson which is an NABP accredited wholesaler.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	DSCSA drugs are purchased only from McKesson which is an NABP accredited wholesaler.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The product is quarantined and the source is contacted for an investigation.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	McKesson is the sole supplier of prescription drugs, other than APIs, and provides all transaction data electronically.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00 _	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	The only CII product used is testosterone API which is a CII only in NY. Orders may be placed only by the PIC, but it is not purchased via CSOS or DEA From 222.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	The only CII product used is testosterone API which is a CII only in NY. Orders may be placed only by the PIC, but it is not purchased via CSOS or DEA From 222.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	No	There is no date and signature or initials of the person checking the order.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	A perpetual inventory is in place and is reconciled monthly.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Diversion would be reported to the PIC and the corporate controller. The local police, the board of pharmacy and the DEA may be contacted if appropriate.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	The CII perpetual inventory (testosterone API) is reconciled monthly and quarterly.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	The printed copy of the complete CS inventory has no date or signature of the pharmacist taking the inventory. There inventory is completed monthly and quarterly, and maintained for the DEA every two years.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	

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		Observation	Notes
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Product is reviewed monthly for expiration dates. There are no OTC products. Short date product is pulled from saleable stock when 30 days from expiration.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Stock is examined monthly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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		Observation	Notes
Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Data is entered by a technician and is updated when information is volunteered by the patient or the prescriber.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The prescriber is contacted for verification.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The pharmacy uses telemedicine platforms for about 90% of their prescriptions. A software system named Verifiable is used to ensure proper licensing for prescribers. BulaLaw is used to ensure the prescription is in compliance with the state laws and regulations for telepharmacy visits for the state to which the prescription is shipped. Please see Doc02_PI for the processes used to ensure prescriptions meet the state requirements.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Electronic prescription capability is for controlled and non-controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A pharmacist verifies data prior to filling and at the time of dispensing using a hard copy or electronic version of the prescription and comparing the information to the data entry.

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		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR is performed by a pharmacist at the date entry point.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	There are no other parameters used.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	Lexicomp may be used.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	PMP data is accessed when it is felt necessary by the pharmacist or when required by NY law.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Only a pharmacist can override a DUR notice. Documentation is in the patient notes or the prescription notes, and using the pharmacist's logon credentials.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan is the integrated drug database used.

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		Observation	Notes
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	A pharmacist reviews the patient profile, the filled prescription, and notes in the file at the final verification.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	The system prints standardized prescription labels based on the most stringent state regulations.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? ***Password protected, access limited by job type, access revoked as appropriate such as upon termination.*** *Record name/brand of pharmacy computer system used.*	Yes	The system is Pharmetika.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	There are no labeled vials used.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

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		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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e-Profile ID: 1642365
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		Observation	Notes
Patient Counseling and Communication	**If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Pharmacists or technicians
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Pharmacists or technicians
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	Pharmacists or technicians
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	There are no delivered prescriptions.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Printed information is provided for all prescriptions as well as a written offer to counsel, using a toll free phone number.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	PPIs are provided with every required prescription. The PPI is manually printed by a technician and part of the final checking process by a pharmacist.

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		Observation	Notes
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	MedGuides are provided with every required prescription. The PPI is manually printed by a technician and part of the final checking process by a pharmacist.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	There are no REMS drugs dispensed.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	No	All patients are provided an offer to counsel, by policy. A refusal of counseling performed is not documented. Actual counseling is documented in the patient's profile.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	Patients can leave a message and be contacted by a pharmacist the next business day.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The PIC oversees the CQI program.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	P & P are electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	No	There is no definition of a QRE. Staff stated they are formulating a definition of a QRE and it will be added to the QRE P & P.
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Initial training includes a review of all P & P including CQI with an assessment of understanding. The annual review is also a review of the P & P and assessment.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Documentation is electronic.

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		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc.).*	Yes	The VP of Compliance, with the PIC or another pharmacist analyzes every event, with a quarterly review of all events.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	Findings are reviewed as part of the quarterly review
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	There is no formulary used.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	QREs are reported to the board of pharmacy if appropriate.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc.?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc.) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		SOP 6.001 Non-sterile Compounding Area Requirements Version 1.0; SOP 6.002 Cleaning and Maintenance Log of the Non-sterile Compounding Area Version 1.0; SOP 6.009 Monitoring of Compounding Area Version 1.0	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		SOP 2.003 Non-sterile Personal Training and Evaluation Version 1.0; P & P 1.04 Training Program SOP Version 0	2, 11

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		SOP 7.004 Required Garb for Non-sterile Compounding Area Version 1.0	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		SOP 8.014 Component Selection Version 1.0; SOP 8.015 Component Receipt and Evaluation Version 1.0	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		SOP 6.009 Monitoring of Compounding Area Version 1.0	4.2, 11
1.6	**Equipment:** The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		SOP 7.001 General Compounding Technique Non-sterile Version 1.1	6.1, 11

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		SOP 9.02 Cleaning Chemical Spills Version 0	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		SOP 10.006 Compounding Record and Master Formula Version 1.0	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		SOP 10.005 Compounding Prescription Label Version 1.0	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		SOP 10.001 Quality Improvement-Performance Improvement Program Version 1.0; SOP 3.37 Designated Person Job Description	11, 12 USP <1163>

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		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		SOP 10.001 Quality Improvement-Performance Improvement Program Version 1.0; SOP 3.37 Designated Person Job Description Version 0	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		SOP 12.002 Patient Drug Delivery Shipping or Pickup Version 1.3	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		SOP 12.002 Patient Drug Delivery Shipping or Pickup Version 1.3	11, 13.2

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		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***	[redacted]	SOP 4.002 Drug Recalls Version 1.0; SOP 7.05 Product Recall Version 0	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4

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		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program. The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes	This is maintained electronically with a new revision number even if only reviewed and not revised.	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11

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		Observation	Inspector Notes	USP Reference(s)
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes	There are no accommodations made.	

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		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes	There are no accommodations made.	3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes	Both disposable and launderable garb are used.	3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	A continuous electronic monitoring and recording system is used.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	Sensors are replaced every 12 months.	4.2

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10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***			4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3

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12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Distilled water is used for rinsing equipment.	4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***	[redacted]	70% isopropyl alcohol is used.	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	The PECs are double filtered HEPA CVEs.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sportive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	Sterile water is used.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

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23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4

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		Observation	Inspector Notes	USP Reference(s)
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes	SDS are electronic.	6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

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	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4

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		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	No		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1

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28.7	MFR contains the reference source to support the assigned BUD.	No	Staff plans to attach the USP reference to the MFR.	7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes	Pharmacist must validate the prescription prior to moving forward.	7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes	Please see Doc04_NS_29.0.	7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14

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29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	Yes	All review is completed by a pharmacist at the end of the compounding process. Weights are transferred electronically to the CR. Measurements for components such as liquids are captured by a photograph and reviewed by a pharmacist. The final product is reviewed by the pharmacist for physical properties and characteristics.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9

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31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A.***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date." If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	Yes		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	Yes		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	Yes		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	Yes		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	Yes		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	Yes		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	No		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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Nonsterile Compounding Inspection for USP <795>

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		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A. If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study. If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range."***	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12

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		Observation	Inspector Notes.	USP Reference(s)
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes	The record is initially hard copy, then digitized, and maintained infinitely.	12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3

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49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	There are no accommodations permitted.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1

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		Observation	Inspector Notes	USP Reference(s)
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration:			

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58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation:** Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	CNSPs reviewed were Diltiazem 2% and Lidocaine HCl 5% in Petrolatum, Naltrexone 1 mg tablets, and Ketamine RDT 100 mg tablets. All CNSPs inspected met expectations.	12

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5. Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	Pharmacist	Pharmacist	Technician	Technician	Technician	Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist	Pharmacist	Technician	Technician	Technician	Notes
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist	Pharmacist	Technician	Technician	Technician	Notes
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP: "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes	Yes	Yes	Yes	

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

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Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

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Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions." If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18

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		Observation	Inspector Notes	USP Reference(s)
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17

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		Observation	Inspector Notes	USP Reference(s)
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		17

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Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		SOP 3.37 Designated Person Job Description Version 0; SOP 8.011 Beyond Use Dating of Sterile Compounded Preparations Version 1	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		SOP 8.025 Sterile Compounding Personnel Training and Evaluation Version 1.1; SOP 8.022 Sterile Compounding Media Fill Test Procedure Version 1.0; SOP 8.003 Required Garb for Cleanroom Facility Access Version 1.0; SOP 8.001 General Aseptic Technique Version 1.1; SOP 8.002 Hand Hygiene-Sterile Compounding Version 1.0	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		SOP 8.003 Required Garb for Cleanroom Facility Access Version 1.0	3, 3.3

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	[redacted]	SOP 6.009 Monitoring of the Compounding Area Version 1.0	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		SOP 8.025 Sterile Compounding Personnel Training and Evaluation Version 1.1	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		SOP 8.025 Sterile Compounding Personnel Training and Evaluation Version 1.1. The SOP does not contain the map, but does reference "the map" which must be used in determination of the sites. The map was reviewed by this inspector.	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		SOP 8.016 Cleaning and Disinfecting Non-HD Sterile Compounding Sterile PEC Version 1.0; SOP 8.017 Cleaning and Disinfecting Non-HD Sterile Compounding Sterile Areas Version 1.0; SOP 9.030 Cleaning and Disinfection of Sterile Compounding Facilities Version 1.1	7, 7.2 Box 7, Box 8

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.	[redacted]	SOP 5.001 General Equipment EML Version 1.1; SOP 5.018 Equipment and Facility Maintenance Version 1.0	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		SOP 8.014 Component Selection Version 1.0; SOP 8.015 Component Receipt and Evaluation Version 1.0	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		SOP 8.028 Compounding Record and Master Formula Version 1.0	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		SOP 8.013 Release Inspections Version 1.0	12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		SOP 8.028 Compounding Record and Master Formula Version 1.0	13

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		Observation	Inspector Notes	USP Reference(s)
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.	[redacted]	SOP 12.002 Patient Drug Delivery Shipping or Pickup Version 1.3	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		SOP 2.03 Records Management SOP Version 0	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		SOP 8.004 Sterilization and Depyrogenation Version 1.0	10

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		Observation	Inspector Notes	USP Reference(s)
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***	[redacted]	N/A	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	21

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		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	No		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	No		1.4

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		Observation	Inspector Notes	USP Reference(s)
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labelling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4

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		Observation	Inspector Notes	USP Reference(s)
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
	Facility Design and Engineering Controls			4
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5

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		Observation	Inspector Notes	USP Reference(s)
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary

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		Observation	Inspector Notes	USP Reference(s)
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	N/A		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	N/A		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	No		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5

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		Observation	Inspector Notes	USP Reference(s)
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
	Establishing BUDs			14
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C). If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12

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		Observation	Inspector Notes	USP Reference(s)
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	N/A	All CSPs prepared are multiple-dose.	13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	No	All CSPs prepared are multiple-dose.	13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	No		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	N/A		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			11
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	N/A		10.1 USP <1228.4>

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		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>

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		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes	CSPs failing the integrity test are discarded.	10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7
	Sterilization and Depyrogenation			10
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes	Only RTU agents are used.	7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes	Sterile water for injection is the only applicable product used.	15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	N/A		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	N/A	Conventionally manufactured single dose vials are not used.	15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1

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		Observation	Inspector Notes	USP Reference(s)
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	No	The compounder failed to disinfect the forceps, which are used to remove the septum from the vial, before they were introduced into the PEC. Forceps were disinfected inside the PEC with an alcohol swab before use. The tip for the syringe used to transfer the compound into the vial was packed in sterile packaging and wiped down before introduction into the SEC, however, the packaging was not wiped before introduction into the PEC.	8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA." If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes	Sterile 70% IPA is used.	8.1

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Compounding of ascorbic acid 500 mg/ml for injection was observed.	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	No		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2

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		Observation	Inspector Notes	USP Reference(s)
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately. If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, Inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing). If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom. If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3

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54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	Accommodations are not permitted.	3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Manual monitoring is performed and recorded.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1

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53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2

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		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	yes		9.1, 9.3.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes." If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
50.1	**APIs:** APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes	Please see Doc05_ST_50.3 for a list of API suppliers.	9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
	Components			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3

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		Observation	Inspector Notes	USP Reference(s)
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Sterile Peridox RTU is used.	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes	Only handles are reusable and are stainless steel.	7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes	Only handles are reusable and are stainless steel.	7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes	Sterile Peridox RTU is used.	7.1.1 Box 7 <1072>

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		Observation	Inspector Notes	USP Reference(s)
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes		Box 2
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2

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45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes	This is documented in the SOP.	2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A		3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes	There are no accommodations made.	3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	N/A	There are no accommodations made.	3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days. If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	N/A		6.3.3 Table 8

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		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, Inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling.. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs. Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations. For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	N/A		6.2.3 Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	N/A	All sampling is incubated and processed internally.	6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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		Observation	Inspector Notes	USP Reference(s)
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A	All sampling is incubated and processed internally.	6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A	All sampling is incubated and processed internally.	6.3

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes	Sampling is performed by internal trained personnel with competencies retained in the employee's file.	6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20

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35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	Yes		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
33.17	**PEC-IVLFZ:** Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video):"*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	N/A		4.2.3
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	A video was provided as part of the environmental report.	4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1

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		Observation	Inspector Notes	USP Reference(s)
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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		Observation	Inspector Notes	USP Reference(s)
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, Inspector should mark as N/A.***	N/A		4.2.4, 5 Table 6
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH).** ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20

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		Observation	Inspector Notes	USP Reference(s)
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	No		4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20

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		Observation	Inspector Notes	USP Reference(s)
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	N/A		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes	Only Category 2 CSPs are compounded.	4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	No		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes	The VP of Compliance is notified by a phone app alarm.	4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least dally on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	Yes		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	No		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]	The current temperature is 68.06 degrees F.	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]	The current humidity is 52.7%.	4.2, 9.3.4, 19.1

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18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes	An electronic continuous monitoring and recording device is used.	4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	An electronic continuous monitoring and recording device is used.	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected. If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	N/A	No carts are used.	4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	N/A	No carts are used.	4.5

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		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is prevented by signage and training.	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is prevented by an interlock.	4.2.1

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		Observation	Inspector Notes	USP Reference(s)
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4

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		Observation	Inspector Notes	USP Reference(s)
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC. If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes	Sterile 70% IPA is used.	4.5

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		Observation	Inspector Notes	USP Reference(s)
13.5	**Category 2 and Category 3:** PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4

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		Observation	Inspector Notes	USP Reference(s)
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	No	Per the PIC and VP of Compliance, different opinions on the line of demarcation from different inspectors and consultants has been given. The facility currently uses a bench as the line of demarcation as directed by a consultant. This line of demarcation is not defining. Please see Photo01_ST12.12 and Photo02_ST12.12.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	N/A	Air returns are low on the wall, however, a smoke study was performed and a video is available.	4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	N/A	Air returns are low on the wall, however, a smoke study was performed and a video is available.	4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes	There is a negative pressure room which is no longer in use and likely will be converted into a positive pressure room.	4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	N/A	The pharmacy is no longer compounding sterile hazardous preparations.	4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3

1983

Performance Improvement Indicator

__ High risk activities	__ Personnel training/competency
__ High volume activities	__ Environmental Safety and Equipment Management
__ Problem prone activity	__ Prevention and Control of Infections
__ Quality control for finished preparations	__ Customer service/Satisfaction
__ Non-Sterile Compounding process	__ Other, Explain:
__ Sterile compounding process	

1986

Complaints/Complaint log	Quarterly		Complaint Log	N/A – team will evaluate each complaint individually.	PI Team to evaluate and initiate corrective actions as appropriate.
Incidents/accidents & adverse events	Quarterly		Incident reports	N/A – team will evaluate each Issue individually.	PI Team to evaluate and initiate corrective actions as appropriate.
Infections	Quarterly		Infection log	N/A – team will evaluate each Issue individually.	PI Team to evaluate and initiate corrective actions as appropriate.
PI annual report:	Annually		N/A	N/A	N/A

1987

PI Activity Schedule

PI Measure/Activity	Frequency	Person Responsible	Data Source	Threshold	Corrective Actions
Capsule weight variance testing is performed for each batch of capsules prepared by the pharmacy. For the records selected above, the auditor will verify the procedure was performed per USP<1163>.	Quarterly Quarterly		5% or 50 compounding records, whichever is less.	95% of CRs for capsules have documented weight variation testing results 100% of the CRs have weight variation testing performed per USP<1163>	PI Team to evaluate and develop a written plan of correction.
Patient satisfaction survey results	Quarterly		100% of returned patient satisfaction surveys	75% of patient report a satisfactory experience	PI Team to evaluate and develop a written plan of correction.
DMEPOS Billing & Coding Errors Audit	Quarterly		100% of Denied claims	0% denied claims	PI Team to evaluate and develop a written plan of correction.
DMEPOS Patient Records	Quarterly		5% of patient records or 50 records, whichever is greater.	95% of patient records are properly documented	PI Team to evaluate and develop a written plan of correction.

As appropriate, each indicator must include and/or address any activities required under state or federal laws or regulations.

Sample PI Activity Schedule
See next page

Establish Thresholds

For each indicator, a threshold for evaluation will be established. A threshold for evaluation should be set to reflect a reasonable level of performance that the company wishes to achieve. For example, for the data element "Adult patients' weights are documented monthly", the threshold 80% may be reasonable. On the other hand, for the data element "Patients receiving penicillin and related antibiotics have medication allergies documented" the threshold should be set at 100%, as even a single omission could prove serious or even fatal.

Note that some measures may not have a threshold at all. Progress on these indicators may be evaluated against a baseline. The company may strive to improve its' performance in a given area by comparing its performance against itself over time.

Plans to Re-evaluate

Each indicator should address plans to re-evaluate if findings fail to meet acceptable thresholds. However, even if an indicator meets acceptable thresholds, the PI team may elect to continue monitoring the indicator, to assure the process remains within acceptable limits.

Documentation of PI Indicators

PI indicators will be documented on the PI Activity Schedule

Corrective Actions

The PI will create a written plan of correction to address any findings that do not meet acceptable thresholds. Each written plan of correction must address:

- An analysis of possible causes the threshold was not met
- The specific corrective actions taken to address the finding(s)
- A time frame for re-evaluation

Corrective Actions will be documented on the PI Plan of Correction Form and will be peer-reviewed for accuracy, sufficiency of information, and improvement.

In the case of a medication error, there shall be both internal and external reporting of the event and the information must be analyzed for trends and patterns.

Any other activities required under state or federal laws or regulation

In this step, the frequency of data collection activities for the indicator must be determined. Consideration must be given to:

- The frequency of PI committee meetings

- How frequently the data is generated:
  - A large quantity of compounding records is generated monthly.
  - Personnel training occurs annually or biannually.

  Whereas an indicator requiring monthly review of compounding records may generate significant data to identify a trend, a monthly review of personnel training records may not.

Assign Responsibility

Each performance improvement will be assigned to one or more individuals. This individual(s) may be responsible for collecting data, organizing data, and/or analyzing data.

Determine Methods of Data Collection

In this step, the methods of data for each data element must be identified. Data collection may include reviews of

- annual patient satisfaction surveys (FM-04 Complaint or Quality Related Event (QRE) Report),
- clinical record
- master formulation records/compounding records
- incident reports,
- equipment maintenance records, etc.

The data collection source should also be carefully considered in defining an indicator. Methods of data collection should allow retrievability of the needed information. For example, an indicator that requires an entire chart review as its' collection source may force the PI committee to expend much of its resources on data collection rather than analysis and improvement.

Ideally, some data collection for improving organizational performance may be incorporated into already existing processes. For example, it may be possible for a computer system to gather PI information in the normal course of business or clinical care.

Care should also be taken to select a collection methodology and sample size which provides the needed information yet does not force the majority of the PI effort to be spent on data collection rather than analysis. If a data element requires excessive or burdensome data collection activities, it may be necessary to modify it or redefine it.

Sample structure indicator: Every prescription bottle has a label.	Sample process indicator: Every prescription has a label stating directions for use consistent with the physicians' orders.	Sample outcome indicator: Patients can clearly understand directions for use of their medication by reading the label.

In select for the PI plan process and outcome measures will be used whenever possible.

Care must be taken to develop performance measures that are objective and measurable. An example of a poor performance measure is "As noted by documentation, all injections meet standards". This measure is not objective, as clearly the results would vary depending on the individual reviewing the record. The example is also not measurable, as it is difficult if not impossible to quantify "meets standards". In this example, the objective may be better measured by focusing on a more easily measurable aspect of injection testing, such as "injections pass a USP<71> compliant sterility test."

Determine Data Elements

Once the PI committee chooses a performance measure, data elements must be selected to allow data collection. The design of the data elements must allow objective and measurable data collection while achieving the intent of the performance measure.

For example, the PI Indicator "Master formulation records contain all required data" can contain the following elements:

- Name, strength and dosage form
- Ingredients and their quantities
- Pertinent calculations
- Equipment and equipment settings used to produce the preparation
- Mixing and/or other pertinent instructions
- Quality control procedures and expected results
- Compatibility and stability information including references when available
- Beyond use date (BUD)
- Container and packaging used for dispensing
- Packaging and storage requirements
- Labeling information including generic name and quantity/concentration of each active ingredient
- A description of the final preparation

Determine Frequency of Activities

- To address a regulatory finding

Indicator Structure

Performance measurement is a critical activity of the PI plan. Using information gathered through this function, the company can make judgments about existing processes, identify opportunities for incremental improvements, identify the need to redesign processes, and decide if improvements or redesigns meet PI objectives.

Each performance measurement activity will contain the following elements:

- A description of indicators to be monitored/activities to be conducted.
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for the findings (Thresholds)
- Who will receive the reports
- Plans to reevaluate if findings failed to meet acceptable limits
- Any other activities required under state or federal laws or regulations

The PI committee may identify many different opportunities for improvement. Because there will probably not be enough time to measure all of them a decision must be made to prioritize which opportunities have the highest priority at the present time. The reason for selecting a particular indicator should be identifiable and rational. The basis for the decision should be consistent with priorities, strategic planning, high volume, high risk or problem prone activities, important functions and the needs of patients, employees, and the company. Documentation of meetings where the PI committee selects indicators should include notes regarding the strategy and rationale for selecting which opportunities are pursued.

Developing Indicators

The company will attempt to develop performance measures to evaluate its progress towards a particular goal. Indicators generally fall into three categories:

- Structure indicators reflect specific characteristics of the organization and define inputs into care or service.
- Process indicators encompass the activities that go into producing an outcome.
- An outcome indicator describes the product of one or more processes.

Examples:

Sentinel events
Benchmarking with external databases and other organizations when information is available
Review of medication errors and adverse drug reactions
Billing and coding errors
Comparison with other measurement resources that may be available such as practice guidelines or standards of care.

PI Committee Activities

Routine Quarterly Activities

Review and as appropriate take action on:

- Patient satisfaction survey results
- Complaints/Complaint log
- Incidents/accidents & adverse events
- Infection log

Review of specific PI indicators as described in the PI schedule attached to this document.

On an ongoing basis, at least one indicator will address one or more of the following important aspects of care:

- An important aspect of care related to the non-sterile compounding process
- An important aspect of care related to the sterile compounding process

Routine Annual Activities

The PI committee will produce an annual written report which includes an evaluation of:

- The effectiveness, quality and appropriateness of care/service provided to clients/patients
- The effectiveness of the overall administrative and fiscal operations
- The effectiveness of all programs including care/service provided under contractual arrangements
- Utilization of personnel
- A summary of the review and revision of policies and procedures and forms used by the organization
- An annual performance improvement report

Unscheduled & As Needed Activities

The PI committee may meet on an as needed basis to perform PI activities, for example:

- To investigate an adverse event

Program Design

Information regarding the results of all mandatory quality assurance and quality control activities will be reported to the PI committee. The PI committee will review these results and use the findings and conclusions of the review to take appropriate action when necessary, including developing indicators to monitor or correct findings on an ongoing basis.

Quality assurance activities and data sources include but are not limited to:

Personnel competency activities and documentation
Routine equipment maintenance and calibration
Documentation of Infections

A quality related event is defined as an event that does not conform to what should normally be or occur with regards to prescriptions medications regardless if it is corrected prior to delivery to the patient or not. Some examples include:

- a dispensing error - wrong drug, wrong strength, script was filled incorrectly
- compounding issues - tablet integrity is lacking, cream is gritty, solution crystallized
- shipping error - shipped to the wrong patient, ice is not included, inserts are missing, incorrect inserts are included

Most of the SOPs in this manual relate to quality assurance activities designed to ensure the quality and safety of compounded preparations.

Quality control activities and data sources include but are not limited to:

Results of finished preparation tests
Reports of Incidents, accidents, infections, unusual occurrences related to the quality of finished preparations
Results of regulatory inspections or insurance audits
Complaint logs
Patient satisfaction survey results
Patient records

Many of the SOPs in this manual relate to assessing and documenting the quality of finished preparations.

Priorities for the PI program to study and improve may be established from a number of sources or combination of sources. Sources may include:

Patient, staff and customer's ideas, needs and expectations
Data from process and outcome measures
Data from quality control measures.
Design and re-design of existing and new processes

Performance Improvement Program

Purpose

This plan outlines a framework for systematically improving organizational performance in regard to the quality of pharmacy services provided by the company.

Priorities

The Performance Improvement (PI) program aims to improve the quality of service to the patient, the working environment for our employees, and the company's financial performance. It is a priority of this program to ensure that all disciplines participate collaboratively in the goal of improving organizational performance.

PI Team

All employees are expected to participate in PI activities when requested, and annually at a minimum. In addition, all management staff must be actively involved in the PI process. Christian Stella, PharmD, ABAAHP, FAAMM is the designated person in charge of overseeing this program

All personnel will receive training related to PI activities and their role. This training will include:

- The purpose of PI activities
- The individual's role in PI activities
- Personnel or person responsible for coordinating PI activities
- Previous and ongoing PI activities

Confidentiality

Everyone participating on the PI committee or otherwise having access to data gathered for PI will adhere to the company's policies and procedures regarding confidentiality of patient information. With the exception of incident reports, which may identify a specific patient, all patient data collected and analyzed will be presented in such a way as to prevent direct identification of the specific patient(s) from which the data was collected.

Use of PI Data for Personnel Evaluations

When PI results or data are relevant to the performance of an individual, they may be used as a component of the evaluation of the individual's competencies.

Attachment E:

SOP AND USP<797> ACKNOWLEDGEMENT

I Sookdeo Ugasir am stating that I have read and understand the non-sterile compounding standard operating procedures (SOP'S) and will abide by them. I also acknowledge I have read the current version of USP<797>.

By signing this form, I also understand that I could be randomly questioned on my understanding of the SOP'S and it is my responsibility to be familiar with and have a clear understanding of them, and how and where to access them. I understand that if I do not abide by the SOP'S that further training and review will be necessary. I have been provided with an opportunity to ask questions or clarify items related to this review. If I willfully and intentionally do not abide by the SOP'S set forth, management will take necessary disciplinary measures.

Employee Signature: _____ Date: 5/31/2024

Witness Signature: _____ Date: 5/31/2024

Attachment D: Viable Air and Surface Testing

For Monthly Air and Surface Testing:

- Attach appropriate sample contact plates label and Certificate of Quality
- Document media serial number and expiration date
- Perform testing starting on site one and precede testing numerically per map ensuring testing is clean to less clean.
- Label with each plate the ID number and date tested.
- Once plates are sampled, place plates face down in a dedicated tote then transport from the sterile suite to tape the samples.
- Ensure the incubator is stabilized at 30°C to 35°C and it is equipped with a secondary temperature sensor. Where the incubators are tracked with alarms 24/7 a paper log is not necessary.
- Insert the plates in the Incubator face down for a minimum of 48 hours.
- Remove the plates carefully, inspect and note the results above.
- Replace samples to be incubated in house a second incubator set to maintain a range of 26°C to 30°C for 5 to 7 additional Days.
- Remove the plates carefully inspect & photo in such a way to clearly prove growth or no growth.
- When removed, the samples or clear photos of the samples shall be thoroughly inspected by Puritechsolutions, CETA number 00011047, who shall provide witness documentation.
- Samples showing growth shall be shipped via overnight delivery to US Micro to perform identification of the organism(s) genus and species. US Micro will provide a written report showing complete results of the identification testing and number of CFUs per sample.
    - The PIC is to be immediately notified if a sample is to be sent out to US Micro.
    - If the results require action, the Board of Pharmacy shall be immediately notified, and production shall be determined per their guidelines.

Attachment C: Sterile Training Documentation - Initial and Annual

Job Description: Sterile Compounding Technician

Technician/Pharmacist: Sookyeo Chagil

General Training Requirements

Requirement	Date Completed	Employee Initials
Read and understand USP<797> and other applicable standards and relevant literature.	5/31/24	S.C.
Watch OSHA video on reading SDS	5/31/24	S.C
Read and understand procedures related to compounding duties.	5/31/24	S.C.
Trained and understands how to interpret Safety Data Sheets (SDS) and if applicable, Certificates of Analysis.	5/31/24	S.C-
Trained and understands how to handle and transport of components and compounded sterile preparations	5/31/24	S.C
Trained and understands how to perform pharmaceutical calculations relevant to their assigned duties	5/31/24	S.C.
Trained and understands the HD list, location of HD list, and how to access it	5/31/24	S.C-
Trained and understands location and use of eye washes and/or showers and spill kits	5/31/24	S.C..
Initial Training: Passes gloved fingertip and thumb sampling test 3 times with a CFU of 0.	5/31/24	S.C
Subsequent Training: Passes a gloved fingertip and thumb sampling test after media fill testing with a CFU count ≤3	5/31/24	S.C.
Acceptably completes a hand hygiene and garbing practices observational assessment	5/31/24	S.C

Employee Signature S.C Date: 5/31/2024

Evaluator Signature: [signature] Date: 5/31/24

Evaluator Comments

Signature of Person Assessed	Sookdeo Chagi	5/31/2024
	Printed Name	Date
Signature of Qualified Evaluator	Lisa Capriola	5/31/2024
	Printed Name	Date

Maintains critical sites in first air. Does not block first air during compounding operations	✓	
Avoids: (a) Leaning into or over the work area (b) Blocking "First Air" between sanitized and/or open containers. (c) Resting hands or forearms on the work area. (d) Coughing over the work area. (e) Rapid movement in the direct compounding area (DCA). (g) Using a PEC as a storage space when not in use. (i) Performing any activities unrelated to compounding	✓	
Disinfects stoppers, injection ports and ampoules with sterile 70% IPA and allows sufficient time to dry.	✓	
Attaches needles to syringe without contact contamination. Avoids touching syringe barrel.	✓	
Does not pick up items any items dropped on floor until sterile compounding operations are complete.	✓	
Punctures vial stoppers and spikes infusion ports without contact contamination. Performs needle punctures with bevel up.	✓	
Applies sterile 70% IPA to the horizontal work surface of the PEC at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding is not be disrupted and the work surface of the PEC is disinfected immediately after compounding.	✓	
Checks the expiration dates and/or color indicators when using autoclaved equipment.	✓	
Disposes of sharps in a medical waste container without risk of needle sticks.	✓	

Exiting the Cleanroom

Ensure that the cart or conveyance that is used to transport components of CSPs or materials from the Buffer areas do not cross the Line of Demarcation separating the "Clean" side of the anteroom from the "Dirty" side.	✓	

Completed Preparations and Quality Control

Visually inspects finished preparations to ensure appearance is as expected, e.g., inappropriate visible particulates, foreign matters, discoloration, or other defects.	✓	
Visually inspects finished preparations to ensure container-closure integrity such as leakage, cracks in the container, or improper seals.	✓	
Performs other quality control checks appropriately per the Master Formulation record	✓	
Labels preparations correctly.	✓	
Performs final check of ingredients used against compounding record.	✓	
Disposes of waste/sharps appropriately	✓	

Leaving the Buffer Room

Item	Yes	No
Removes personal protective equipment on the dirty side of the ante area	✓	
Removes gloves and performs hand hygiene	✓	
Removes gown and discards it, or hangs it on hook if it is clean and can be used the same shift	✓	
Removes and discards mask, head cover, and beard cover prior to leaving compounding lab.	✓	
Removes shoe covers when leaving the compounding lab	✓	

Evaluator Comments

Signature of Person Assessed	Printed Name	Date
	Sookjoo Chagi	5/31/2024
Signature of Qualified Evaluator	Printed Name	Date
	Lisa Capriola	5/31/2024

Attachment A:

Performance Audit of Hand Hygiene and Garbing for Sterile Compounding - Initial and Annual

Employee Name:	Sookdeo Ojagir
Position:	Sterile Compounding Technician

Directions: A qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if not applicable or N/O if activity was not observed. The person assessed is immediately informed of all unacceptable activities and shown specific corrections.

Entering Compounding Area

Item	Yes	No
Presents in a clean appropriate attire and manner. Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests, jewelry). Does not enter if sick or exposed to illness.	✓	
Removes all cosmetics because they shed flakes and particles.	✓	
Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails and extenders) must not be worn.	✓	
Wipes eyeglasses if worn.	✓	
Does not wear earbuds or headphones. Does not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.	✓	
Brings no food of drinks into ante-area or buffer areas	✓	
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓	
Dons shoe covers one at a time, placing the covered or designated show on the clean side of the line of demarcation as appropriate.	✓	
Dons beard cover if necessary.	✓	
Dons head cover assuring that all hair is covered.	✓	
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓	
Dries hands and forearms using lint-free towel	✓	
Selects appropriately sized gown examining for tears or other defects	✓	
Dons gown and ensures full closure	✓	
Gown sleeves do not contact floor or other surfaces during donning	✓	
Enters buffer room without contaminating hands	✓	
Disinfects hands again using waterless alcohol-based hand rub and allows hands to dry thoroughly without waving or blowing prior to donning sterile gloves	✓	
Dons appropriately sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips	✓	
Examines gloves to ensure that there are no defects, holes, or tears.	✓	

Observational Checklist: Gowning and Garbing Competency

Employee: Sookdeo Chagai

Observer: Lisa Capriola

Date: 5/31/2024 Time: 8:00AM

Prep Room Gowning	
Observed Action	**Compliant (Y/N)**
Steps on tacky mat before entering prep room	Y
Dons hair net and beard cover if applicable	Y
Dons face mask	Y
Dons shoe covers on shoe at a time while crossing the line of demarcation	Y
On clean side of Anteroom	Y

Anteroom Gowning	
Observed Action	**Compliant (Y/N)**
Wash hands (soap with water)	Y
Dry hands (lint-free wipes)	Y
Dons disposable lab coat	Y

Buffer Room Gowning	
Observed Action	**Compliant (Y/N)**
Disinfect Hands (alcohol-based surgical hand scrub)	Y
Allow hands to dry	Y
Don sterile gloves	Y
Disinfect gloves (sterile 70% IPA)	Y

Observational Checklist: Sterile HD Compounding Performance Audit

Job Description: Sterile Compounding Technician

Technician/Pharmacist: Sookhoo Chagi-J Date: 5/31/2024

Employees will demonstrate the following prior to compounding independent from the trainer or PIC.

Employees are to be retested annually.

Check Yes/No	General Sterile HD Compounding Knowledge
✓	Wears appropriate PPE.
✓	Compounds HDs only in an appropriate PEC.
✓	If the ISO-5 PEC is co-located with a PEC for presterilization procedures, sterile compounding is not performed at the same time as particle generating activities.
✓	Covers work surface with a sterile plastic backed preparation mat.
✓	Only introduces the materials for one patient or batch into the PEC at a time.
✓	Disinfects exteriors of containers, vials supply etc. with SIPA prior to introducing into PEC.
✓	If hands are removed from PEC during compounding, gloves are disinfected with SIPA and allowed to dry prior to re-entry.
✓	Works with equipment and materials as far back in the cabinet as practical.
✓	Follows best practices for compounding in a vertical air flow device. Does not block first air. Disinfect hands with SIPA every 30 minutes while compounding.
✓	Syringes used to measure HDs are no more than ¾ full. • Expels bubbles in a manner that prevents aerosolization. Uses syringes with luer lock fittings.
✓	Compounding technique is adjusted to prevent aerosolization and volatilization.
✓	Deactivates and decontaminates the exterior of finished compounded preparations prior to removing them from the PEC.
✓	Deactivates and decontaminates all glassware, equipment and utensils per the established procedure prior to removing from PEC.

Signature PIC or authorized personnel _____ Date: 5/31/2024

Employee Signature: _____ Date: 5/31/2024

2006

Name of PIC Conducting the Inventory: _____ _____

Print **Signature**

Date and Time Started: _____

Date and Time Finished: _____

Name of Pharmacy: _____

Address of Pharmacy: _____

Controlled Substance Inventory

Name of Drug (Strength and Dosage Form If Applicable)	Raw Material?	Finished Product?	Total Number of Containers	Total Count of Individual Units	Lot Number	Date

6.1 This inventory is to also be conducted when there is a change of Pharmacist-in-Charge, change of address, any moving or construction, suspected theft or loss, natural disaster, at the request of a regulatory agency, or any other time the Pharmacist-in-Charge or owner(s) deems necessary.

VI. References:

- US Dept. of Justice, Drug Enforcement Administration Office of Diversion Control-Pharmacist Manual Section I-VIII
- SOP 5.03 - Controlled Substance Prescription Monitoring Program
- SOP 5.04 - DEA Form 222 Ordering/ Processing/ Receiving

VI. Attachments:

1.0 Attachment 1: Controlled Substance Inventory Template

- A file for all other drugs dispensed (non-controlled and those in Schedules III, IV, and V). If this method is used, a prescription for a Schedule III, IV, or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If the Pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

- Electronic Prescription Records

  - If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

  - Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other federal or state law or regulation applicable to pharmacists or pharmacies.

  - Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

4.0 Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of 21 CFR 1311. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

5.0 Invoices/Receipts: All receipts and/or invoices for controlled substances whether they are for raw materials or finished products are to be signed by the person accepting the package and dated. These receipts will be furnished to the pharmacy's controller and maintained for record keeping purposes.

6.0 An annual inventory of all controlled substances is to be conducted during the month of May of each calendar year. The inventory is to be conducted by the Pharmacist-in-Charge. The inventory shall include raw materials as well as finish products. Attachment 1 is to be completed. Each inventory is to be filed and maintained for record keeping purposes.

3.0 Records and inventories of Schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of Schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records.

Retrievable Records

1.0 Readily retrievable records are defined as:

- Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time.
- Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

2.0 Central Recordkeeping: A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/ her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located (Appendix K). Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification. Central recordkeeping requirements are described in 21 CFR 1304.04. Central recordkeeping permits are no longer issued by the DEA.

3.0 Prescription Records: Pharmacies have two options for filing prescription records under the C.F.R. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the Pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be readily retrievable for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

- Paper Prescriptions Records Option 1 (Two separate files):
  - A file for Schedule II controlled substances dispensed
  - A file for Schedules III, IV and V controlled substances dispensed
- Paper Prescriptions Records Option 2 (Two separate files):
  - A file for all Schedule II controlled substances dispensed

Pharmacy	Standard Operating Procedure		
Title	Controlled Substance – Records Retention		
Policy No.	8.04	Revision	1

Prepared by/Date: Connor Longo, PharmD. 6/13/2024	Approved by/Date: Lisa Capriola, PharmD. 6/13/2024

8.04 Controlled Substance - Records Retention

I. **Purpose:** This procedure describes the Pharmacy's record retention requirements for any Pharmacy Controlled Substance, records, reports, or forms.

II. **Scope:** This procedure applies to all Pharmacy personnel responsible for record retention of controlled substance records and compliance with state and federal regulations.

III. **Definitions:**

Controlled Substance Records: For this procedure, include the following:

- Executed and unexecuted official order forms: DEA Form 222 or the electronic equivalent
- Power of Attorney authorization to sign order forms (See Section 13.0, FM-8)
- Receipts and/ or invoices for Schedules III, IV, and V controlled substances
- All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of controlled substances dispensed (i.e., prescriptions, Schedule V logbook)
- Reports of Theft or Significant Loss (DEA Form 106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
- Records of transfers of controlled substances between pharmacies
- DEA registration certificate
- Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005
- Controlled Substance Program Monitoring records

IV. **Procedure:**

General Requirements

1.0 The Pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the Pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

2.0 All required records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials.

- Dissatisfied ____

- Very dissatisfied ____

4. Prescription Information

- Did the pharmacist provide clear instructions and information about your medication?

  - Yes, very clear ____

  - Somewhat clear ____

  - Not very clear ____

  - Not clear at all ____

5. Recommendation

- How likely are you to recommend our pharmacy?

  - Very likely ____

  - Likely ____

  - Neutral ____

  - Unlikely ____

  - Very unlikely ____

6. Additional Comments

- Please share any additional comments, suggestions, or concerns you have about our pharmacy:

Customer Service Survey

Thank you for choosing Precision Compounding Pharmacy & Wellness Inc. for your healthcare needs. Your feedback is valuable to us as we strive to provide excellent service. Please take a moment to complete this survey.

1. Overall Experience

- How satisfied are you with your overall experience at Precision Compounding Pharmacy?
  - Very satisfied ____
  - Satisfied ____
  - Neutral ____
  - Dissatisfied ____
  - Very dissatisfied ____

2. Staff Interaction

- How would you rate the friendliness and helpfulness of our staff?
  - Excellent ____
  - Good ____
  - Average ____
  - Poor ____
  - Very poor ____

3. Wait Time

- How satisfied were you with the time you had to wait for assistance or to receive your prescription?
  - Very satisfied ____
  - Satisfied ____
  - Neutral ____

When the pharmacy's number is dialed, there are two prompts to direct the caller to the proper line. One prompt is to reach our call center and the other is for verbal prescriptions. If the improper line is dialed, the pharmacy staff can transfer the call to the proper line needed. The ending of the menu prompt directs the caller to "hang up and dial 911," in the case of a severe medical emergency where urgent assistance is required, such as hospitalization.

The website also provides the pharmacies email that is accessible even after hours of operations.

Attachment 1.0: Customer Service Survey will be sent out to every email or phone in the pharmacies database that belongs to a patient of which the pharmacy has filled a prescription for in the previous calendar year. The responses will be gathered and interpreted by the compliance team. The compliance team will analyze the data and create trends, identify problems, implement corrective actions, etc. with the goal in mind of creating a better patient experience and to identify and resolve any problems. If an employee needs to be evaluated, documentation of such is to go in their employee profile.

The pharmacy's website does have information/education about the business operation. The pharmacy declares that all online prescription drug/device advertising complies with federal law, the FD&C Act, as well as both federal and state regulations.

V. References: N/A

VI. Attachments:

1.0 Customer Service Survey

Pharmacy	Standard Operating Procedure		
Title	Customer Service		
Policy No.	4.01	Revision	1

Prepared by/Date: Connor Longo, PharmD. 6/13/2024	Approved by/Date: Lisa Capriola, PharmD. 6/13/2024

4.0 Relations Customer Service

4.01 Customer Service

I. Purpose: This procedure describes how Pharmacy personnel can create an excellent customer service relationship with patients and partners.

II. Scope: This procedure applies to all personnel.

III. Definitions: N/A

IV. Procedure: Establishing an excellent customer service relationship between patients/partners and Pharmacy personnel is essential to providing optimal pharmaceutical care, which is the cornerstone of the Pharmacy. To provide optimal pharmaceutical care, Pharmacy personnel must create a feeling of trust, confidence, and support with patients/ customers that extends far beyond prescription dispensing.

Pharmacy personnel are responsible for the quality of customer service, which includes:

- Adhering to both state and federal pharmacy regulations
- Ensuring accuracy and quality in prescription receipt, processing, and dispensing
- Maintaining confidentiality of electronic Protected Health Information (ePHI) and Individual Identifiable Health Information (IIHI)
- Complying with Pharmacy policy and procedure
- Listening before responding to questions and communications from customers, Pharmacy personnel, and health care professionals
- Responding, always, in a professional and courteous manner
- Treating customers with respect and courtesy
- Resolving customer complaints quickly and efficiently
- Working to support Pharmacy team goals
- Establishing trust and confidence with all Pharmacy personnel

The pharmacy makes their hours of operation known on its website, https://mypcphealth.com/, and verbally at request. Pharmacists' availability is only guaranteed during hours of operation unless in an emergency. As stated on the website, the pharmacy is available 24/7 for emergencies only via texting the pharmacies text-able number.

- Disperse an equal portion of the homogenous powder mixture into the tablet machine
- Utilize the capsule machine to properly place and press the tablets
- Label appropriately with batch label and bring the completed product to the appropriate validation bin
- Clean the hood and all used materials when finished compounding
- Weigh 3 tablets separately. The final weight of each suppository shall not be less than 90% and not more than 110% of the theoretically calcu
- Visually inspect compounds before validating

› Details

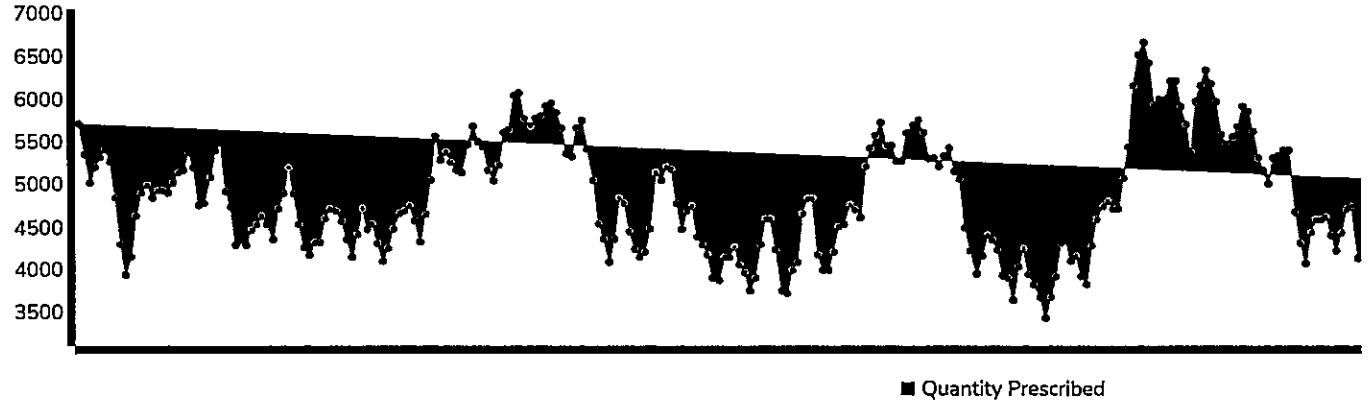
Stability Supporting Documentation
Chemical Compatibility
Packaging
Storage Instructions
Store in the original container, tightly sealed, protected from direct sunlight and moisture. Store at room temperature. (20° to 23°C (68° to 77°F))
Final Appearance
Homogenous orange solid dispersion tablet. The final weight of each capsule should fall between 90 and 110% of theoretically calculated weight
SOP/Reference Documentation

Documents

Category: Method of suitability

Name	Note
USP 795 BUDs for CNSPs.png	

Anticipatory Compounding Limit: 6745 - 2024-03-18 - 2024-04-17 Download



History

Date	User		Note
2023-04-08 10 am	Justin Tamayo		
2023-04-08 11 am	Connor Longo	Formula re-activated	
2023-04-08 11 am	Justin Tamayo		
2023-04-08 12 pm	Jennifer McDonald	Formula re-activated	
2024-03-22 4 pm	Lisa Capriola		
2024-03-22 4 pm	Kevin Von	Formula re-activated	
2024-03-22 4 pm	Kevin Von		
2024-03-22 5 pm	Lisa Capriola	Formula re-activated	
2024-07-12 12 pm	Lisa Capriola		
2024-07-12 12 pm	Connor Longo	Formula re-activated	

2016

Naltrexone 1mg Tablet [LDN1]active

Formula Name
Naltrexone 1mg Tablet
Formula ID
LDN1
NDC
99000928498

☑ Add as ingredient?
Formula Type
Tablets
Dosage Form
Oral Tablet
Route of Administration
Oral route

☐ Sterile

Therapy Class

Task Points
Required Time
Location
Stability Span
180
Status: active
Verified: 2024-07-12 by Connor Longo
Last Modified: 2024-07-12 by Lisa Capriola

Auxiliary Labels

Ingredients

Description

Require Measurement Check
Quantity Sufficient
Quantity

Naltrexone HCl Powder
Code: Nal

☐ Check
☐ QS
1.2084 gm

LFA Orange Firmapress
Code: LFAO

☐ Check
☐ QS
323.724 gm

Total Weight: 324.932

Quantity: 1200
Units Tablet
Instructions

Tasks

- Clean the hood and all materials necessary for compounding
- Weigh, measure or count the calculated amount of each ingredient needed
- Triturate particles in the appropriate mortar and pestle until homogenous powder mixture is obtained. Glass for powders, ceramic for tablets or
- Properly set up the tablet machine with the desired tablet size and the necessary amount filled.

2018

Pharmacy Name: Precision Compounding Pharmacy & Wellness Inc.

Pharmacy Address: 2657 Merrick Road, Bellmore, NY 11710

NABP Business e-Profile ID: 1642365

VPP Inspection Date(s): 5/29/2024-5/30/2024

Sharing Acknowledgment: | By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Page No.	VPP Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Action Taken	Attachment (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	20	51.00	Our VP of Compliance, Chief Operating Officer, and Controller all meet to implement a plan of action to ensure all invoices (controls and non-controls) are signed and dated upon reciept to confirm accuracy. This as	6/13/2024	Y	P&P 8.04 Controlled Substance - Records Retention SOP
Updates/New SOPs or P&Ps	20	57.00	Our VP of Compliance, Chief Operating Officer, and Controller all meet to implement a plan of action to ensure a complete template is created and added to our SOPs to be utilized for all future controlled susbtance	6/13/2024	Y	P&P 8.04 Controlled Substance - Records Retention SOP
Updates/New SOPs or P&Ps	28	87.02	Improvement-Performance Improvement Program. This SOP is the the detailed outline of our quality program that goes over everything from	6/6/2024	Y	SOP 10.001 Quality Improvement-Performance Improvement Program
Updates/New SOPs or P&Ps	30	93.00	Service SOP that will be distrubted annually. This SOP is the overview of the pharmacies policy regarding customer service, its importance, how to	6/13/2024	Y	P&P 4.01 Customer Service SOP
Other	55	28.7	USP BUD reference has been uploaded to the MFR's for non-sterile compounds	6/13/2024	Y	Example MFR (page 2 hyperlink USP 795 BUDs for CNSPs.png) and USP 795 BUDs for CNSPs (reference in hyperlink)
Clarification or Further Explanation	99	12.0	SEC. We disagree and are disupting the "No" inputted on the report that we do not have a proper clean room suite. The item number 12.6	N/A	N	
Clarification or Further Explanation	103	12.12	We have received conflicting answers on what is the best choice for a line of demarcation from our first VPP inspection, to a consultant firm, to a New York State Board of Pharmacy inspector, to thist most recent VPP	8/31/2024	N	
Clarification or Further Explanation	119-120	31.0 and 31.2	We dispute the answer of No to both of these item numbers. All presterilization procedures are preformed in a double HEPA CVE hood located in the ante room. These hoods are inspected every six months	N/A	Y	Presterilization CVE Hoods in Ante Room
Other	174	58.5	This employee under went immediate evaluation of aseptic technique and stertile compentencies. They were retrained and not permitted to continue compounding until they met the satisfaction of the PIC, VP of	5/31/2024	Y	S. Uzagir Retraining and Reevaluation 5.31.2024
Photos	198	71.11	The addition of the wording, "This is a multidose vial," has been added to the labels of all CSPs	6/4/2024	Y	Unit Dose Label Sample

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

2019

Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
81.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	There have been no spills in the last year.

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Hazardous Drugs- Handling in Health Care Settings

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)			
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C PEC and the solution used does not alter the product label.	Yes	

2020

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2021

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
Dispensing, Packaging, and Compounding Processes			
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	N/A	
75.00	Clean, dedicated (not used for non HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	This applies only to non-sterile compounding. There is no sterile hazardous compounding.
75.02	**Recommendation:** When compounding, a plastic backed preparation mat is placed on the C PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	No	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	No	
75.02.03	At the end of a shift	No	
76.00	APIs or other powdered HDs are handled in a C PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

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Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
Labeling, Packaging, Transport, and Disposal			
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	Yes	

2022

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2023

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	There have been no HD damaged packages received.

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
Environmental Quality and Control - Surface wipe sampling			
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	Yes	
62.01	Interior of C-PEC and equipment within the C-PEC	Yes	
62.02	Pass-through chambers	N/A	The facility performs only non-sterile HD compounding and there is no pass through.
62.03	Surfaces in staging or work areas near the C-PEC	Yes	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	Yes	
62.05	Areas immediately outside the HD buffer room or the C-SCA	Yes	
Receiving			
63.00	**Recommendation:** HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	N/A	HDs are unpacked in the HD storage area.
65.00	A spill kit is readily accessible in the receiving area.	Yes	

2024

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	Sterile HD compounding has been discontinued.
61.00	If the negative pressure HD buffer room is entered through a positive pressure non HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	Sterile HD compounding has been discontinued.
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	Sterile HD compounding has been discontinued.
61.02	Indicate how HD contamination is minimized:		Sterile HD compounding has been discontinued.
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	N/A	Sterile HD compounding has been discontinued.
61.02.02	Use of sealed containers	N/A	Sterile HD compounding has been discontinued.
61.02.03	Other, *describe*	N/A	Sterile HD compounding has been discontinued.

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
59.02	A handwashing sink is at least one meter or more away from the C-PEC	N/A	Sterile HD compounding has been discontinued.
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		Sterile HD compounding has been discontinued.
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	Sterile HD compounding has been discontinued.
60.01	The buffer room has fixed walls.	N/A	Sterile HD compounding has been discontinued.
60.02	The buffer room is externally vented.	N/A	Sterile HD compounding has been discontinued.
60.03	The buffer room has HEPA filtered supply air.	N/A	Sterile HD compounding has been discontinued.
60.04	The buffer room has at least 30 ACPH.	N/A	Sterile HD compounding has been discontinued.
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	Sterile HD compounding has been discontinued.
60.06	The anteroom has fixed walls.	N/A	Sterile HD compounding has been discontinued.
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air.	N/A	Sterile HD compounding has been discontinued.
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	Sterile HD compounding has been discontinued.

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2027

Hazardous Drugs Handling in Health Care Settings

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
55.01.07	LAFW (not for antineoplastics)	N/A	Sterile HD compounding has been discontinued.
55.01.08	CAI (not for antineoplastics)	N/A	Sterile HD compounding has been discontinued.
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	N/A	Sterile HD compounding has been discontinued.
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	N/A	Sterile HD compounding has been discontinued.
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	N/A	Sterile HD compounding has been discontinued.
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	N/A	Sterile HD compounding has been discontinued.
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	Sterile HD compounding has been discontinued.
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	Sterile HD compounding has been discontinued.

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
52.03	Is the C PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding?** If yes, complete 55.01 61.02.03. If no, skip to 62.	No	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding:**		Sterile HD compounding has been discontinued.
55.01.01	CACI	N/A	Sterile HD compounding has been discontinued.
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	Sterile HD compounding has been discontinued.
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	Sterile HD compounding has been discontinued.
55.01.04	Class II BSC, Type B1	N/A	Sterile HD compounding has been discontinued.
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	Sterile HD compounding has been discontinued.
55.01.06	Class III BSC	N/A	Sterile HD compounding has been discontinued.

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2029

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding:**		
50.02.01	Class I biological safety cabinet (BSC)	N/A	
50.02.02	Class II BSC	N/A	
50.02.03	Containment ventilated enclosure (CVE)	Yes	The PECs are double filtered HEPA CVEs.
50.02.04	Compounding aseptic containment isolator (CACI)	N/A	
50.02.05	Other, describe	N/A	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	No	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	Yes	
52.00	Does the pharmacy use the same C PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is **nonsterile HD compounding** only "occasional"? / *If yes, please describe frequency and quantity.*	N/A	
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	

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		Observatio	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C PEC operates continuously if it supplies some or all of the negative pressure in the C SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01 54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	

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Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C SCA]).	N/A	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	
45.00	If non antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non HD inventory, there is a written policy/SOP addressing it.	N/A	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C PEC located in a C-SEC room.	Yes	
47.01	The C SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C SEC).	Yes	
43.00	**Storage:** Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	Storage is off the floor and on shelves with a raised lip to help prevent a fall and package breakage.
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	N/A	
40.00	***Recommendation:*** *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	No	There is an available onsite generator, however, in the event of a power loss, the negative pressure non-sterile area would lose status before the generator is operable
41.00	**Receipt:** Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	HD drugs are unpacked in the hazardous drug storage area.
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	The area is negative pressure.
41.01.01	Neutral	No	
41.01.02	Negative	Yes	

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Hazardous Drugs- Handling in Health Care Settings

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C PEC or contained in a sealable bag for discarding outside the C PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	P-95 fit-tested masks are used.
35.01	Fit-tested NIOSH-certified N95 respirator;	No	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
35.03	Full-facepiece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	No	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE:** Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit tested, when required).*	Yes	P-95 fit-tested masks are used.
33.01	Fit-tested NIOSH-certified N95 respirator;	No	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	No	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
30.00	**Gowns:** The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

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Hazardous Drugs - Handling in Health Care Settings

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
29.00	**Gloves:** The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 – or its successor – and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	N/A	Sterile HD compounding has been discontinued.
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	N/A	Sterile HD compounding has been discontinued.
26.06	Administration, if applicable;	N/A	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Yes	

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Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

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		Observatio	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	N/A	Sterile HD compounding has been discontinued.
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

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		Observatio	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training --*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	

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		Observatio	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	Yes	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

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		Observatio	Notes
13.19	Administering SOPs, if applicable	N/A	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	Yes	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	

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Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	The non-sterile C-PEC is used.
13.14.03	container is placed on a plastic-backed preparation mat;	Yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

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		Observatio	Notes
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened:**		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened**:		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PECs], containment secondary engineering control [C SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	Yes	
13.11.03	Frequency	Yes	

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Hazardous Drugs Handling in Health Care Settings

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Notes
10.02	**Dispensing**: Counting or packaging tablets and capsules	Yes	
10.03	**Compounding/other manipulations:** Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	N/A	
10.05	**Spills**: Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	All SOPs and P & P are electronic and available to all personnel on a shared Google drive.

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Hazardous Drugs Handling in Health Care Settings

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		Observatio	Notes
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	The assessment of risk was reviewed March 22, 2024.
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
10.01	**Receiving:** Contacting HD residues on packaging, work surfaces, floors	Yes	

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Hazardous Drugs Handling in Health Care Settings

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	Yes	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	

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Hazardous Drugs Handling in Health Care Settings

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	N/A	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	N/A	
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	Please see Doc07_Haz_3.00.
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	The list was reviewed March 22, 2024.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	

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e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observatio	Notes
General Information and Scope:			
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Please see Doc06_Haz_1.01.
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	No	
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	No	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	N/A	

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GLOSSARY USP <797>
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

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GLOSSARY USP <797>
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

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GLOSSARY USP <797>
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.

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GLOSSARY USP <797>
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance*.
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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GLOSSARY USP<797>
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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GLOSSARY USP<797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#6									
#7									
#8									
#9									
#10									

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Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.
5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).

Aseptic Manipulation Competency (Section 2.3)

USP requirements:
1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.
2. The pharmacy conducts media-fill testing as described in Box 2.
3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.
4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.
5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.
6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.
7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.
8. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	Yes	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	Yes	

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#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. 2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row. 3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth. 4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days. 5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands. 6. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	

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#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#6								
#7								
#8								
#9								
#10								

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.
Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding or *support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2, 2.1, 17 Table 2, Table 3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	N/A		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	N/A		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	N/A		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	N/A		18.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Precision Compounding Pharmacy & Wellness Inc. dba Precision Compounding Pharmacy

e-Profile ID: 1642365

Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>

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		Observation	Inspector Notes	USP Reference(s)
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes		12.2, 12.3
	CSP Packaging, Shipping and Transport			19
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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		Observation	Inspector Notes	USP Reference(s)
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	Yes		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes		12.3 Table 13 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	Yes		12.2 USP <71>, <1223>

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***<u>Parenterals</u>*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***<u>Large volume parenterals</u>*** ***2% or 10 containers, whichever is less*** ***<u>Non-parenterals (eye drops, inhalation, pellets, etc.)</u>*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes		12.2, 14.2.3 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14

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74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution. If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3

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Inspection Date: 05/29/2024 - 05/30/2024

		Observation	Inspector Notes	USP Reference(s)
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RLS (USA) Inc

Physical Address: 945 N. Edgewood Ave, Suite A-1

City: Wood Dale State: IL Zip: 60191

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 630-595-6642 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 630-595-8583 Contact Email: chicago@rls.bio

Website: rls.bio

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): John Perino

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Arasally Rodriguez	NV Pharmacist Registration #: 24298
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: RLS (USA) Inc

Mailing Address: 255 Primera Blvd, Ste 440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: licensing@rls.bio

Contact Person Name: Kristin Anson

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Regulatory Assurance (title) for RLS (USA) Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Glenn Sullivan

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/10/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Glenn Sullivan, Director of Regulatory Assurance

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/10/24

Date

Board Use Only	Date Received: _____	Amount: 500.00 | V# 2078

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 945 N. Edgewood Ave, Suite A-1

City: Wood Dale State: IL Zip: 60191

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 630-595-6642 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 630-595-8583 Contact Email: chicago@rls.bio

Website: rls.bio

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): John Perino

Supervising/Managing Pharmacist NV Pharmacist Registration #: N/A

Name of Person with direct knowledge of compounding procedures: John Perino

Email of Person with direct knowledge of compounding procedures: john.perino@rls.bio

Telephone of Person with direct knowledge of compounding procedures: 630-595-6642

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Radiopharmaceuticals only prepared or compounded in compliance with USP <825>

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of Radiopharmaceuticals in compliance with radiation safety ALARA principals.

8. How often do you perform glove fingertip and medial fill testing?

Every 12 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Immediate notification of the PIC, investigation for cause, corrective action(s) identified and taken as needed to prevent re-occurrence, retraining as required, retesting performed and passing results obtained prior to initiating or resuming product preparation or dose drawing duties.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

All new hire personnel performing sterile compounding must be licensed or registered in compliance with local regulations. Initial training is assigned based on job title/duties performed through an electronic platform. Personnel are trained on all policies and procedures associated with their job duties prior to performing those duties. Annual retraining is tracked, completed, and maintained using the electronic platform.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached SOP's 6.4.1, 6.4.1.1 and 6.4.1.2

12. Who performs the sterile compounding process at your facility?

All products are prepared by or under the direct supervision of the licensed, authorized nuclear pharmacist on duty.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The PIC is responsible and accountable for the sterile compounding process.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

RLS (USA) Inc. is a Nuclear Pharmacy dispensing radiopharmaceuticals in compliance with USP <825>. All transportation of prepared radiopharmaceuticals are completed by trained staff or contracted courier services in climate controlled vehicles in DOT-7A, Type A certified packaging designed and tested to maintain the quality and integrity of the product. Where temperature monitoring is required. RLS (USA) Inc. utilizes appropriate ColdMark Indicators to ensure proper temperature is maintained during shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

N/A

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Perino

Name of Person who Completed the Form

PIC

Title

Signature (copies or stamps not accepted)

9/7/24

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

File Number 7206-604-9

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

RLS (USA) INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON SEPTEMBER 12, 2019, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 17TH *day of* APRIL *A.D.* 2024 .

Authentication #: 2410803870 verifiable until 04/17/2025
Authenticate at: https://www.ilsos.gov

SECRETARY OF STATE

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
054.021668
051.286793

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
03/31/2026

LICENSED PHARMACY

NUCLEAR, STERILE COMPOUNDING

RLS (USA) INC
JOHN PERINO
945 N EDGEWOOD AVE STE A1
WOOD DALE, IL 60191-1252

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

19097715

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4348997

Illinois Department of Financial and Professional Regulation

Division of Professional Regulation

JB Pritzker
Governor

Mario Treto, Jr.
Secretary

Camile Lindsay
Acting Director
Division of
Professional
Regulation

CERTIFICATION OF LICENSURE

John Perino
945 N Edgewood Ave Ste A1
Wood Dale, IL 60191-1252

Licensee:	RLS (USA) INC
Number:	054.021668
Profession:	LICENSED PHARMACY
Date of Issuance:	08/12/2021
Expiration Date:	03/31/2026
License Status:	ACTIVE
License Method:	NON-EXAM
Disciplinary History:	Has not been disciplined

This document is a certified copy of the records maintained and kept by this department in the regular course of business as of 07/17/2024

Camile Lindsay

Camile Lindsay
Acting Director
Division of Professional Regulation

07/17/2024
Date

Refer to the Department's Web Site at IDFPR.Illinois.gov to verify professional licenses via License Look-Up.

RLS
RADIOISOTOPE LIFE SCIENCES

2106

Corporate Officer List

Name and Title	Business Address and Phone Number	Home Address and Phone Number		
Stephen Belcher Chief Executive Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] Tivoli Dr, Miramar Beach, FL 32550 Phone: [redacted]		
Mannon George Bankson III (Trey) Chief Operating Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] Falls Crest Place, Auburn AL 36830 Phone: [redacted]		
Glenn Sullivan Director of Regulatory Assurance	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted] E. Main Street, Saint Paris, OH 43072 Phone: [redacted]		

RLS (USA) Inc. Ownership Structure

RLS (USA) Inc., a Delaware corporation headquartered in Florida, is owner and operator of 31 radiopharmacies in the United States and was formed through the spin out of General Electric's radiopharmacy in 2020. RLS (USA) Inc. is the owner and operator of the pharmacy subject to this application.

RLS Group, Ltd., is a Bahamas-chartered entity which, since 2020, serves as the holding company for RLS(USA) Inc. As shown on the attached organizational diagram and stock certificate, RLS Group, Ltd. is the 100% owner of RLS (USA) Inc. RLS Group, Ltd. participated in providing initial acquisition financing for the 2020 spin out from General Electric and is otherwise inactive, has no employees, and in particular does not participate in the management of, or control operations in, any RLS (USA) Inc. radiopharmacy, including the radiopharmacy subject to this application. RLS Group, Ltd. has no separate office and receives mail at: RLS Group, Ltd., c/o RLS (USA) Inc., 255 Primera Blvd., Suite 440, Lake Mary, FL 32746. RLS Group, Ltd.'s registered agent (as required by Bahamas law) is: RLS Group, Ltd., c/o King & Co., Second Floor, Olde Towne Marina, Sandy Port, New Providence, P. O. Box N-4825, The Bahamas.

2108

RLS (USA) INC.

INCORPORATED IN THE STATE OF DELAWARE

TOTAL AUTHORIZED ISSUE
2,000 SHARES $0.01 PAR VALUE
COMMON STOCK

SHARE CERTIFICATE NUMBER: 1
NUMBER OF SHARES: 2,000

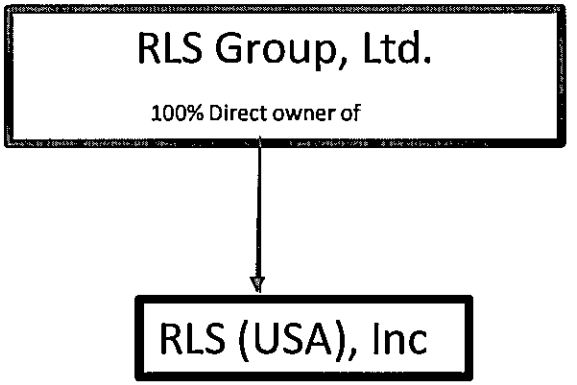
This is certifies that **RLS GROUP LTD.**, a company organized under the laws of the Commonwealth of The Bahamas with Registration Number 202690 B, is the registered owner of **2,000 (two thousand)** fully paid and non-assessable shares of the above Corporation transferable only on the books of the Corporation by the holder thereof in person or by a duly authorized Attorney upon surrender of this Certificate properly endorsed.

Witness, the seal of the Corporation and the signatures of its duly authorized officers.
January 11, 2019.

GERHARDUS VAN NIEKERK
VICE PRESIDENT

WERNER GRUNER
PRESIDENT

Ownership Org Chart



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RLS (USA) Inc

Pharmacy/Wholesaler License # (if applicable) 054.021668

Physical Address 945 N. Edgewood Ave, Suite A-1

City Wood Dale State IL Zip 60191

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 630-595-6645 Website rls.bio

Licensing Company Email licensing@rls.bio

Section 2: Personal Information

First Otha Middle _____ Last Bright

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] W Stewart Ridge Dr

City Plainfield State IL Zip 60585

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Purdue University			8/1982 - 5/1989
Address	**City**	**State**	**Zip**
128 Memorial Hall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
RLS USA Inc			
Business Address	**City**	**State**	**Zip**
945 N Edgewood Ave Suite A-1	Wood Dale	IL	60191
Phone	**Title**	**Number of Employed Hours**	
630-595-6642	Business Unit Manager	52,000	
Description of Duties			
Managed the operation and logistic side of the pharmacy. Provide guidance with our SOP and USP 797 and 825			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Otha Bright, **certify that as the designated representative for**

RLS (USA) Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ob I am at least 21 years of age;
3. ob I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ob I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ob I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ob I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ob I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

٢

Otha Bright

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Otha Bright

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, OTHA BRIGHT, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/5/24

Date

Subscribed and Sworn to before me this 5th day of September, 2024

Carol Jean Dean

Notary Public Signature

CAROL JEAN DEAN
OFFICIAL SEAL
Notary Public - State of Illinois
Commission No. 992134
My Commission Expires June 10, 2028

(Seal)

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Nuclear USP <825> Inspection Form

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Nuclear Pharmacy Inspection

Business e-Profile ID:	1803196		**Inspection Information**
Legal Business Name:	RLS (USA) Inc.	**Conference Call Date:**	4/29/2024
Doing Business As (DBA):	N/A	**Start Time; 24-hour format (13:00)**	12:00
Address:	945 North Edgewood Ave Ste A1	**End Time: 24-hour format (13:00)**	14:16
City:	Wood Dale	**Onsite Inspection Date(s):**	5/2/2024
State:	Illinois	**Start Time(s): 24-hour format (13:00)**	5:20
Zip Code:	60191	**End Time(s): 24-hour format (13:00)**	11:45
Telephone number:	630-595-6642	**Inspector Name(s):**	Howard Kramer RPh
Toll free number:	N/A	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	630-595-8583	**Observer Name/Affiliation (If applicable):**	N/A
Website:	www.rls.bio	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all-inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.
Nuclear-59.00, 59.01, 115.01, 339.00 and 340.00

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday	3:00	7:00	
Monday	23:30	15:00	
Tuesday	23:30	15:00	
Wednesday	23:30	15:00	
Thursday	23:30	15:00	
Friday	23:30	15:00	
Saturday	1:00	9:30	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Designated Person	Otha Bright, Jr.	otha.bright@rls.bio	278319
Designated Person	N/A	N/A	N/A
Pharmacist in Charge	Otha Bright, Jr.	otha.bright@rls.bio	278319
Radiation Safety Officer (RSO)	Arasally Rodriguez	arasally.rodriguez@rls.bio	242723
HIPAA privacy officer	Jayne Carney Senecal (corporate)	jayne.carneysenecal@rls.bio	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current
1	Otha Bright, Jr.	PIC	Y
2	Arasally Rodriguez	RSO/Pharmacist	Y
3	Sara Steelglove	Technician	Y
4	John Perino	Pharmacist	Y
5	Tiffany Sisson	Courier	N/A
6	Ubaldo Medina Sisson	Courier	N/A
7	Edward Garcia	Courier	N/A
8	Tyler Carter-Koonce	Courier	N/A
9	Ryszarda Turala	Technician	Y
10	Brian Worden	Courier	N/A

There were two couriers in addition to the above personnel.

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Business Licensure Information for State of Residence and Federal (Board of Pharmacy, State Controlled Substance, State Radiation Control Agency, Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), Nuclear Regulatory Commission (NRC))

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number / Expiration Date
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	RLS (USA) INC JOHN PERINO	Pharmacy	054.021668 Exp: 3/31/2026
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	RLS (USA) INC OTHA BRIGHT	Wholesale Drug Distributor	004.004913 Exp: 12/31/2024
Illinois Emergency Management Agency and Office of Homeland Security Office of Nuclear Safety	RLS (USA) Inc.	RAM	IL-01052-01 Exp: 3/31/2028

Inspector Notes: Facility non-resident licenses are held in Indiana and Wisconsin. The wholesale distributor license is maintained and was previously used for the distribution of I-123 Ioflupane, a C-II drug. Per the PIC, the wholesale distribution license was required by the DEA. The WD license is no longer used. There is no wholesale distribution at this time. There is no insulin stocked and no ReliOn insulin was observed. There are no platforms used that are a marketplace for pharmacies to buy, sell, or bid on overstock and short-date prescription drugs. There is no semaglutide compounded.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_Gen8.01_RLS(USA)Inc	Facility's response to deficiencies noted in the IMEA inspection report dated 3/21/2023
Doc02_Gen17.00_RLS(USA)Inc	The last internal audit, deficiencies and action plan
Photo01_Nuclear115.01_RLS(USA)Inc	Rust and deterioration on the sink located outside of the anteroom

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	Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT		Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT
Ship/Deliver (in state)	X	Manufacturer	
Ship/Deliver (out-of-state, list below)	X	Wholesale Distributor (WD)	X
Central Fill/Processing/Shared Services		Handles Positron Emission Tomography (PET) Preparations	X
Institutional		Handles Nonsterile Preparations	X
Free Standing	X	Handles Sterile Preparations (eg including minor deviations)	X
Telepharmacy		Handles Investigational New Drugs (IND)	
Provide radiopharmaceuticals for 'Office Use'		Handles Blood Preparations	X
Provide radiopharmaceuticals for 'Physician Use'	X	Handles Volatile Isotopes (Xe-133 gas, liquid I-131 NaI)	X
Outsourcing Facility		Provide radiopharmaceuticals for Immediate Use	
Handles Sterile dispensing and repackaging	X		

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Facility Size (in Square Feet) and Number of PECs	
Total Nuclear Pharmacy size:	11,000
Nonsterile Processing area size:	117
Sterile Processing Anteroom size:	98
Sterile Processing Clean/Buffer Room size:	1020
Blood Preparations Processing Room size:	135
Size of the decay storage area:	242
Sterile number of PECs:	4
Nonsterile number of PECs:	2
Blood Preparations - number of PECs (eg BSC):	3
Segregated Radiopharmaceutical processing area (SRPA) size:	N/A
Number of Hot Cells:	0

Personnel	
Total Nuclear Pharmacists:	5
Total Nuclear Pharmacy Technicians:	2
Total Interns or Students:	1
Total Other Personnel:	10
Total Nuclear Pharmacist Hours Per Week:	200
Total Nuclear Pharmacy Technician Hours Per Week:	80
Board Certified Nuclear Pharmacist (BCNP):	3

Volume Dispensed	
Total Prescriptions Dispensed/day:	285
% Veterinary	0 %
% Controlled Substances	0%
% Nonsterile Compounded	15%
% Sterile Compounded	0%
% of Sterile preparations	85%
% of Nonsterile preparations	0%

Volume Distributed	
Total Orders Distributed/day:	15
% Veterinary	0%
% Controlled Substances	0%
% Nonsterile Compounded	0%
% Sterile Compounded	100%
% of Sterile preparations	0%
% of Nonsterile preparations	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific - is not labeled with the patient name at the pharmacy. HD means drugs on the National Institute for Occupational Safety and Health (NIOSH) list of HD such as hormones, chemotherapy, etc. There are currently no radiopharmaceuticals which are considered NIOSH HDs.

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)	68	35	Week of 4/22/2024 through 4/28/2024
Indiana (IN)	9	0	Week of 4/22/2024 through 4/28/2024
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)	58	0	Week of 4/22/2024 through 4/28/2024
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
	General Pharmacy		
1.00	Is the Designated Person present for the inspection?	Yes	
2.00	Is the PIC (or nuclear pharmacy manager/director) present for the inspection? *If no, list the nuclear pharmacist on duty.*	Yes	
3.00	Are photographs allowed during the inspection (no Protected Health Information (PHI))?	Yes	
	General Operations and Licensure		
4.00	Are pharmacy licenses, permits and registrations (state, controlled substance, DEA, etc.) posted?	Yes	All facility and personnel licenses are posted on a bulletin board in the office area.
5.00	Is the RSO the same as is listed on the radioactive materials (RAM) license?	Yes	
6.00	Is the PIC an Authorized Nuclear Pharmacist (ANP) on the RAM license or other retrievable documentation as confirmed by the NRC or agreement state?	Yes	
7.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	N/A	There has been no inspection by the Illinois Board of Pharmacy.
7.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	N/A	
8.00	Is the most recent NRC (and/or state radiation control agency) inspection report available for review? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	Yes	The last Illinois Emergency Management Agency inspection was dated 3/21/2023. The PIC is not aware of any regularly scheduled inspections by Illinois or any state.
8.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Please see Doc01_Gen8.01 for the inspection deficiencies and the facility's response to and action plan for the noted deficiencies.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
9.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
10.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
11.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
12.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	The DEA inspected the facility on 8/11/2014 and left a Notice of Inspection Form DEA-82. The DEA does not regularly inspect the facility.
13.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
14.00	Has the pharmacy been inspected by the Environmental Protection Agency (EPA), Department of Transportation (DOT) or any other outside agency? *If yes, indicate the inspection date and note any deficiencies related to pharmacy practice.*	Yes	The DOT inspected the facility on 2/9/2006. The deficiency documented as a "Probable Violation" was "Failure to provide security awareness to a new employee. The company has no record of security awareness training for Dorsey Chappelle, hired Sept 2005." The deficiency was corrected.
15.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	The pharmacy holds an accreditation from The Joint Commission for Home Care Accreditation # 535863. dated 9/9/2022 and valid for 36 months.
16.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold?	No	

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
17.00	Were any deficiencies detected on the last internal audit? *List date of last audit and note any deficiencies found and action plan to correct.*	Yes	The last internal audit was dated 12/14/2023. Please see Doc02_Gen17.00 for the full report including deficiencies and the corrective action plan.
Policy and Management			
18.00	Are policies and procedures for the program maintained in the pharmacy in an immediately retrievable form? *Indicate if hard copy, electronic, or both.*	Yes	P & P are electronic and on the corporate shared drive.
19.00	Are the P&Ps reviewed and updated regularly? *Indicate the review frequency and who performs the reviews.*	Yes	The Management of Change program requires the PIC to review the P & P quarterly and make suggestions for improvement.
20.00	Are systems in place for the ongoing monitoring of state and federal laws/regulations for changes? *Give details of the system and resources, or indicate if it is a corporate process and who is responsible overall as well as at the site.*	Yes	The corporate RSO reviews state and federal regulations and communicates them to the facility. The PIC receives bulletins and emails from the boards of pharmacy for the licensed states.
21.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is part of the corporate P & P.
22.00	Does the pharmacy maintain all required records, including but not limited to prescription files, on site? *Record how long records are kept. If not on site, where?*	Yes	All records are maintained onsite. Record retention varies with the record type, with prescription records maintained for five years.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
23.00	Does the pharmacy have access to appropriate law references including state and federal regulations (including state regulations for all states in which the facility is licensed and NRC)? *Indicate if they are hard copies or are accessed online (demonstrate access) or both.*	Yes	Access to law references is both hard copy and electronic.
24.00	Does the pharmacy have access to other references as required by state law? (eg appropriate dosage and toxicology references). *Indicate if they are hard copies or are accessed online or both.*	Yes	Dosage and toxicology references are both hard copy and electronic.
25.00	Does the pharmacy have access to appropriate practice specific references? Nuclear, geriatric, pediatric, etc. *List and indicate if hard copy or online or both.*	Yes	Practice-specific references are both electronic and hard copy. The most frequently used are the hard copies of Fundamentals of Nuclear Medicine, by Stabin, and Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine, by Kowalsky.
26.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] up to date and available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
27.00	Does the pharmacy have a hazardous waste handling and collection system? *Indicate how often waste is collected and the vendor(s) used.*	Yes	Hazardous waste is picked up by Stericycle on as needed basis.
	Product Ordering, Receipt and Inventory		
28.00	Is the pharmacy restricted to buying prescription drugs from certain WDs or manufacturers?	Yes	
28.01	If restricted, does the PIC approve the vendors? *If not, who does approve (corporate)?*	No	
29.00	Are all orders received when the pharmacy is open or placed in a secure area if the pharmacy is closed?	Yes	Orders are received only when the pharmacy is staffed and a pharmacist present.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
30.00	Does the pharmacy purchase any compounded radiopharmaceuticals from other entities for dispensing to patients? *If so, describe which compounded radiopharmaceuticals and from where they are purchase (collect name and license of other entity).*	No	
31.00	Does the pharmacy make any sterile or nonsterile compounded radiopharmaceuticals using bulk powder or liquid (APIs)? *Indicate bulk products and vendors used.*	No	
32.00	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	No	
33.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities, and are adjustments tracked?*	Yes	Only a pharmacist can adjust quantities and all entries and adjustments are tracked.
34.00	Are orders generated and sent by the computer for prescription products, including controlled substances? *Who can alter the orders before they are sent?*	No	A pharmacist must process the order. There are standing orders for generators.
35.00	Does the pharmacy maintain required inventories (such as change in PIC, theft/loss, etc)? *Indicate which.*	N/A	There are no controlled substances stocked.
36.00	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	The Board of Pharmacy would be notified and local law enforcement may be contacted dependent on the circumstances.
37.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*	Yes	There is a monthly inventory and reconciliation with the system records.
38.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe process (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	There is a perpetual inventory in the pharmacy system.
39.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *Describe what happens if products are damaged.*	Yes	Damaged RAM material requires a notification to the RSO who determines handling. Non-RAM material is quarantined and the source is notified of the issue.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
40.00	How are outdated, damaged, or recalled products segregated? *Indicate how often the pharmacy checks for out-of-date products.*	Yes	The system maintains expiration dates and expiration dates are reviewed at the time of use. There is no regularly scheduled review of expiration dates.
41.00	Are non-RAM expired or damaged products destroyed on site? *View documentation. If "no", note the name of the reverse distributor.*	No	Stericycle is the reverse distributor.
	Prescription/Order Processing		
42.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Indicate whether there is a central fill/central processing agreement in place.*	No	
43.00	Does the pharmacy obtain a copy or verify of the RAM license (of the facility to which the radiopharmaceutical will be delivered) issued by the State Radiation Control Agency or the NRC?	Yes	
44.00	Is there a procedure to obtain a RAM license for the facility when a license cannot be obtained or verified?	Yes	The facility is contacted for license verification or a timely renewal letter. The state may be contacted for validation of the facility RAM license if necessary.
45.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The facility uses WebOLO for online ordering.
46.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored off site .*	Yes	The system is backed up daily, and maintained on corporate servers and a cloud.
47.00	Is there a continuity plan should the system become inoperable? *Describe how data will be retrieved.*	Yes	There is a local backup system that allows full operation. When the main system is operable, the data from the backup system must be re-entered.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
Patient Profiles and Communication			
48.00	Does the patient information gathered include patient contact information, age or date of birth, and gender, as required by the State Board of Pharmacy?	Yes	Only the patient's name is normally provided. The facility may require and request the patient's weight for some doses.
49.00	For therapy doses, does the pharmacy receive appropriate information to assess correct dosage, such as geriatric or pediatric weight-based doses, as required by the State Board of Pharmacy and/or Radioactive Materials Regulatory Agency?	Yes	
50.00	Does the pharmacist perform an evaluation of the dose, safety, and intended use of the preparation to be compounded?	Yes	The radiologist may be contacted for information if necessary.
51.00	Does the pharmacy take back prescription drugs from customers (eg clinic, prescriber, etc.)? If so, describe.	Yes	Unused doses may be accepted from prescribers or clinics and destroyed.
52.00	Are providers instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Yes	
Patient Confidentiality			
53.00	Is there a HIPAA policy in place for employees, vendors, and contractors?	Yes	
54.00	Do employees deemed nonessential to patient care have access to confidential patient information, such as delivery personnel, etc.?	No	

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
55.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked.*	Yes	Passwords are assigned by corporate IT with access based on the employee's role. Access is revoked upon termination of employment. All access into the system is tracked.
56.00	Are confidential documents shredded? *Indicate if In-house or by a service and list service in notes if applicable.*	Yes	Shred-It is used.
57.00	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	There are no vials used.
58.00	Does the crisis plan include security of paper and electronic patient information?	Yes	
Prescription Packing and Transporting			
59.00	Does the pharmacy utilize employee drivers to deliver prescriptions to patients and/or facilities?	Yes	
60.00	Does the pharmacy utilize other services/carriers to deliver prescriptions to patients and/or facilities? *Indicate carriers used.*	No	
61.00	Is there is a tracking system in place to verify delivery of prescription products? *Indicate if signatures obtained or how tracked.*	Yes	An Apple Encore GPS tracking system is used with iPhones assigned to each driver. The package barcode is scanned and the barcode at the facility is scanned and must be a match.
62.00	Are deliveries of RAM directly to a secure location at a health care facility?	Yes	
63.00	Is only authorized packaging used?	Yes	
64.00	Is the packaging tamper-evident?	Yes	WBC packages are padlocked. Other deliveries use shrink wrap on the pig and zip ties on the carton.

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
Personnel Qualifications			
65.00	Is there a process for periodic verification of validity of personnel licenses (registrations)? *Describe the process.*	Yes	The PIC maintains a spreadsheet of all personnel licenses and reviews the primary source verification website annually.
66.00	Are all personnel wearing name tags that clearly identify if they are a pharmacist or a technician? *What about other positions?*	Yes	All employees wear a picture ID with name and position held.
67.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, the training and certifications are verified. *View documentation.*	N/A	
68.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?	Yes	
69.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The maximum number of licensed personnel working at any time is one technician and three pharmacists
70.00	Do employees undergo background checks upon hire? *Indicate if performed periodically for existing employees.*	Yes	Only initial criminal background checks are performed.
71.00	Do employees undergo drug testing upon hire? *Indicate if performed periodically for existing employees and if it is random, for cause, or both.*	Yes	There is a voluntary post-accident drug testing policy.
72.00	Is there a performance review process and is it documented? *If yes, how often?*	Yes	The performance review is an annual process.
73.00	Is a procedure for corrective or disciplinary action in place and documented?	Yes	

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
	Facility and Security		
74.00	Is entry to prescription product storage and processing areas limited to task-critical employees?	Yes	
75.00	Is entry into the handling areas limited to task-critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	Yes	
76.00	Are drugs secured to prevent unauthorized removal or access?	Yes	
77.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT manages the security system which consists of magnetic door sensors, motion detection devices, and glass break sensors. The main door is a keyed lock with key pass access for all other doors. Access is based on the employee's job description and role. Alarms are sent by phone call and text message to the PIC, and a phone tree if there is no response.
78.00	Does the pharmacy have cameras? *If yes, record how long images are retained.*	Yes	Images are maintained for 90 days or more.
79.00	Does anyone have access to the pharmacy after hours in the absence of the pharmacist? *Explain.*	No	
80.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break?	Yes	
80.01	If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?	Yes	

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Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Nonsterile Radiopharmaceuticals			1.1
1.00	Does the pharmacy compound nonsterile radiopharmaceuticals? *If so, list which of the following do they compound (eg Oral Capsules, oral solutions, other (if other, list those products in the notes)).*	Yes	Oral capsules and oral solutions are compounded.	1.1
2.00	Does the pharmacy obtain conventionally manufactured nonsterile drug products for dispensing? *If so, list those products in the notes.*	No		1.1
3.00	Does the pharmacy obtain compounded nonsterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No		1.1
	Sterile Radiopharmaceuticals			1.2
4.00	Does the pharmacy compound sterile radiopharmaceuticals? *If so, list which of the following do they compound in the notes. (eg, intravenous, intrathecal, intraperitoneal, subcutaneous, intradermal, inhalation, ophthalmics, intra-organ instillations)*	Yes	The pharmacy compounds intravenous and inhalation radiopharmaceuticals.	1.2
5.00	Does the pharmacy obtain conventionally manufactured sterile drug products for dispensing? *If so, list those products in the notes.*	Yes	In111 DTPA	1.2
6.00	Does the pharmacy obtain compounded sterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No		1.2
7.00	Does the pharmacy compound sterile preparations involving one or more nonsterile components?	No		1.2
8.00	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (eg filtration with bubble point testing) performed prior to dispensing?	N/A		1.2
9.00	If the pharmacy compounds injectable sterile preparations involving one or more components that are not certified to be pyrogen-free, is pyrogen testing performed prior to dispensing?	N/A		1.2

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
Immediate Use of Sterile Radiopharmaceuticals				3
10.00	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?	No		3
11.00	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?	N/A		3
12.00	Does handling for immediate use sterile radiopharmaceuticals in an ambient environment lacking primary and secondary engineering controls when intended for a single patient meet the following requirements? as applicable:	N/A		3
12.01	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?	N/A		3
12.02	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (eg, NDA, ANDA)?	N/A		3
12.03	Are dispensing of drug products produced under an approved IND or RDRC protocol?	N/A		3
12.04	Are manipulations for any unit doses (eg, decreasing the dosage, needle changes) or dispensing for one patient (eg, withdrawing a dose) ?	N/A		3
12.05	Are preparations labeled for administration within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first?	N/A		3
12.06	Are all components involved (eg, Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first?	N/A		3
12.07	Does the pharmacy indicate that dose pooling (combining doses from two or more syringes to meet one patient's need) is performed as immediate use? Is any residual activity that remains is immediately discarded and not utilized for any other patient?	N/A		3

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
12.08	Does pharmacy staff follow proper hand hygiene and garbing?	N/A		3
12.09	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?	N/A		10.4
12.10	Does the pharmacy follow 12.2 Labeling for labeling?	N/A		12.2
12.11	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (eg, radiolabeling food) during the time of use?	N/A		
12.12	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?	N/A		
12.13	Are the number of steps or punctures limited?	N/A		
12.14	Does the pharmacy require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (eg, aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)?	N/A		4.1
12.15	Is adding non-radioactive, sterile and commercially manufactured pharmaceutical(s) only applicable if performing immediate use. *While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (eg, lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to.*	N/A		
12.16	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?	N/A		

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		Observations	Notes	USP Reference(s)
12.17	If performed, is dose splitting done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area? *Note where this is performed.*	N/A		
Personnel Qualifications, Training, and Hygiene				4
13.00	Are personnel trained to work with radiopharmaceuticals per policies and standard operating procedures (SOPs) authorized by an ANP or AU (eg physician)?	Yes		4
14.00	Do personnel follow these policies or SOPs of the ANP or AU (eg physician) and work under their supervision?	Yes		4
14.01	Are personnel trained in blood-borne pathogens (as appropriate)?	Yes		4
15.00	Are individuals entering a handling area properly garbed and maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals?	Yes		4
15.01	Are individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (eg, rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) reported to their supervisor?	Yes		4
15.02	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?	Yes		4
16.00	Have all personnel of reproductive capability who handle, or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?	Yes		4
17.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?	Yes		4

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		Observations	Notes	USP Reference(s)
18.00	Can personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas)?	Yes		4
19.00	Can personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting?	Yes		4
	Aseptic Qualifications		***Note to Inspector:*** *Check two (2) employee personnel files for documentation (1 RPh and 1 Tech), as appropriate*	4.1
20.00	Do personnel prove competency under the observation of a designated person, as applicable to their jobs, prior to performing radiopharmaceutical aseptic tasks (that are beyond immediate use). *Note– these can be completed at a different site if all SOPs are identical for the applicable job function.*	Yes	Files were reviewed for John Perino, pharmacist and Ryszarda Turala, technician.	4.1
21.00	Do the minimum qualifications include the following?	Yes		4.1
21.01	Aseptic technique with a documented assessment (written or electronic)	Yes		4.1
21.02	Garbing and hand hygiene, as defined by policies and SOPs	Yes		4.1
21.03	PEC cleaning and disinfecting	Yes		4.1

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		Observations	Notes	USP Reference(s)
21.04	Gloved fingertip and thumb sampling	Yes		4.1
21.05	Media-fill testing (not required for non-compounding personnel)	Yes		4.1
	Gloved Fingertip and Thumb Sampling			4.1
22.00	Is gloved fingertip and thumb sampling required for all personnel who enter and perform tasks in an ISO Class 5 PEC (eg, aseptic manipulations, cleaning the PEC)?	Yes		4.1
23.00	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?	Yes		4.1
23.01	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony- forming units (cfu)?	Yes		4.1
24.00	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?	Yes		4.1
25.00	Is the gloved fingertip and thumb sampling performed with touch plates or other devices (eg, plates, paddles, or slides) that contain a general microbial growth agar [eg, trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (eg, lecithin and polysorbate 80) which support both bacterial and fungal growth?	Yes		4.1

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		Observations	Notes	USP Reference(s)
26.00	Per P&P review, gloves are not disinfected immediately before touching the sampling device.	Yes		4.1
27.00	Is a gloved fingertip and thumb sample from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?	Yes		4.1
28.00	Are the plates incubated in an incubator at 30°–35° C for no less than 48 h, and then at 20°–25° C for no less than 5 additional days?	Yes		4.1
	Media-Fill Testing			4.1
29.00	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?	Yes		4.1
30.00	Is testing reflective of the actual manipulations to be carried out by the individual and simulate the most challenging and stressful conditions to be encountered in the worker's duties?	Yes		4.1
31.00	Are media-fill tests documented as defined by the facility's policies and SOPs?	Yes		4.1
32.00	*Recommendation: Are media-fill tests be performed at the end of a work session in the PEC.*	Yes		4.1
33.00	Are media-fill tests performed with a commercial source of soybean–casein digest medium?	Yes		4.1
34.00	Do those performing sterile-to-sterile processing activities start with sterile media?	Yes		4.1
35.00	Do those performing nonsterile-to-sterile compounding use a nonsterile soybean–casein digest powder to make a solution?	N/A		4.1

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		Observations	Notes	USP Reference(s)
35.01	Is dissolved nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution?	N/A		4.1
35.02	Is the final media manipulated in a manner that simulates nonsterile-to-sterile compounding activities?	N/A		4.1
35.03	Is the final media prepared with at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation?	N/A		4.1
36.00	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?	Yes		4.1
37.00	Once the media-fill simulation is completed and the final containers are filled with the test medium, are the media filled containers incubated for 7 days at 20°–25° C followed by 7 days at 30°–35° C to detect a broad spectrum of microorganisms? Note: Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days.	Yes		4.1
38.00	In the event of failure, are results of the evaluation and corrective actions documented and the documentation maintained to provide a record and long-term assessment of personnel competency?	Yes		4.1
39.00	Do media and components used include the following?	Yes		4.1
39.01	manufacturer	Yes		4.1
39.02	expiration date	Yes		4.1
39.03	lot number	Yes		4.1
40.00	Does the documentation include at a minimum the following?	Yes		4.1

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		Observations	Notes	USP Reference(s)
40.01	starting temperature for each interval of incubation	Yes		4.1
40.02	dates of incubation	Yes		4.1
40.03	results	Yes		4.1
40.04	name of the person evaluated	Yes		4.1
40.05	evaluation date	Yes		4.1
40.06	evaluation time	Yes		4.1
	Reevaluation, Retraining, and Requalification			4.2
41.00	Do personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile radiopharmaceuticals?	Yes		4.2
42.00	Are all failures, retraining, and re-evaluations documented?	Yes		4.2
43.00	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?	Yes		4.2

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		Observations	Notes	USP Reference(s)
	Timing of Reevaluation and Requalification			4.2
44.00	**Visual observation:** Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures both initially, and then at least once every 12 months?	Yes		4.2
45.00	**Gloved fingertip and thumb sampling:** Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing).	Yes		4.2
46.00	**Media-fill testing:** After initial qualification, is a media-fill test of all personnel engaged in sterile radiopharmaceutical processing performed at least every 12 months (in conjunction with gloved fingertip and thumb sampling)?	Yes		4.2
47.00	**Cleaning and disinfecting:** Does the pharmacy retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner?	Yes		4.2
48.00	**After a pause in sterile radiopharmaceutical processing:** Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?	Yes		4.2
49.00	**Sterile compounding using a nonsterile drug substance or components:** Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?	N/A	There are no nonsterile drugs or components used.	4.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Ancillary Personnel			4.3
50.00	Are personnel who are authorized to be within the sterile processing area and do not handle sterile preparations required to complete all training and testing other than training on media-fill testing ?	N/A	There are no personnel authorized to be within the sterile processing area who do not handle sterile preparations.	4.3
51.00	Do other personnel or visitors (eg, auditors, regulators, student observers) comply with garbing and gloving SOPs without the need to prove competency?	Yes		4.3
	Hand Hygiene and Garbing for Immediate Use Preparations			4.4
52.00	**Hand hygiene:** Do personnel wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands?	Yes		4.4
53.00	**Garbing:** Immediately after hand hygiene, do personnel don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA?	Yes		4.4
54.00	Is a different lab coat worn to care for a patient than the coat/gown used for radiopharmaceutical preparation?	N/A	There is no patient care area.	4.4
	Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area			4.5
55.00	Before entering the SRPA or buffer area, do personnel remove all the following (as applicable)? *(Radiation dosimetry devices are allowed, as required by the RAM license).*	Yes		4.5
55.01	Outer garments (eg, bandanas, coats, hats, jackets, sweaters, vests)	Yes		4.5
55.02	All cosmetics	Yes		4.5

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		Observations	Notes	USP Reference(s)
55.03	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing	Yes		4.5
55.04	Nail products (eg, artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}	Yes		4.5
55.05	Ear buds	Yes		4.5
55.06	Headphones	Yes		4.5
56.00	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?	N/A	There is no SRPA.	4.5
57.00	Do personnel don shoe covers, head/hair/facial hair cover(s) and face masks? Note – these items are donned in an order that eliminates the greatest risk of contamination, as defined in facility SOPs.	Yes	Dedicated shoes are used, or shoe covers for visitors.	4.5
58.00	Does the process before entering the buffer area or SRPA include the following?	Yes		4.5
58.01	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner	Yes		4.5
58.02	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels	Yes		4.5
58.03	Electronic hand dryers are not permitted	Yes		4.5

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		Observations	Notes	USP Reference(s)
58.04	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub	Yes		4.5
58.05	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. *Note: Disposable gowns are preferred.*	Yes	Gowns are laundered and not disposable.	4.5
58.06	If reusable gowns are used, a clean gown is donned daily.	Yes		4.5
58.07	Aseptically don sterile, powder-free gloves. Gloves completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped.	Yes		4.5
59.00	Does the routine process include the following?	No		4.5
59.01	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?	No	The pharmacist observed during compounding frequently used sterile 70% IPA to sanitize the gloves. However, on one occasion during the observation, the pharmacist used the IPA, made notes on the documents, and then re-entered the hood without further sanitizing.	4.5
59.02	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?	Yes		4.5
59.03	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?	Yes		4.5
59.04	Remove the gloves	Yes		4.5
59.05	Repeat antiseptic hand cleansing using an alcohol-based hand rub	Yes		4.5
59.06	Don new sterile gloves	Yes		4.5
59.07	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites	Yes		4.5

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		Observations	Notes	USP Reference(s)
60.00	Do exiting processes for buffer area or SRPA include the following?	Yes		4.5
60.01	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of	Yes		4.5
60.02	New PPE is used for each re-entry	Yes		4.5
60.03	Gowns may be re-used within the same shift if maintained to minimize contamination (eg away from sinks)	Yes		4.5
60.04	Gowns are in a classified area or,	Yes		4.5
60.05	Gown are kept in (or immediately outside of) the SRPA	N/A	There is no SRPA.	4.5
	Facility Design and Environmental Controls			5.1
61.00	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?	Yes		5.1
62.00	Is the facility is well-lighted?	Yes		5.1
63.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes		5.1
64.00	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?	Yes		5.1

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		Observations	Notes	USP Reference(s)
65.00	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?	Yes	Temperatures are recorded manually once daily.	5.1
66.00	Are the temperature readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes	Temperatures are recorded manually once daily.	5.1
67.00	Are the temperature readings reviewed as described in the facility's SOPs?	Yes		5.1
68.00	Are free-standing air conditioners used within the classified area or SRPA?	No		5.1
69.00	Are temperature monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
70.00	*Recommendation: The humidity in classified areas and SRPA are continuously maintained at a relative humidity (RH) below 60%.*	Yes		5.1
71.00	Is the humidity monitored in the classified areas and SRPA each day that it is used, either manually or by a continuous recording device?	Yes	The humidity is recorded manually once daily.	5.1
72.00	Are the humidity readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes	The humidity is recorded manually once daily.	5.1
73.00	Are the humidity readings reviewed as described in the facility's SOPs?	Yes		5.1
74.00	Are free-standing humidifiers/dehumidifier used within the classified area or SRPA?	No		5.1

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		Observations	Notes	USP Reference(s)
75.00	Are humidity monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
76.00	Is the designated person responsible to ensure the following?	Yes		5.1
76.01	Does each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?	Yes		5.1
76.02	Are ISO Class 5 PECs located, operated, maintained, monitored, and certified to have appropriate air quality?	Yes		5.1
	Types of Secondary Engineering Controls and Design:			5.1
77.00	Were placement of doors, door surfaces, and movement of the door, all of which can affect airflow, considered when designing doors for a sterile radiopharmaceutical processing facility?	Yes		5.1
78.00	Are tacky surfaces not used in ISO-classified areas?	Yes		5.1
79.00	Are the PEC located in a SEC?	Yes		5.1
80.00	When the PEC is located in an SEC which is an ISO-classified buffer room with an ante room, does all of the following apply?	Yes		5.1
80.01	Is the ISO-classified ante-room and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?	Yes		5.1

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		Observations	Notes	USP Reference(s)
80.02	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?	Yes		5.1
80.03	Is the air supplied to the classified areas introduced through HEPA filters that are located in the ceiling?	Yes		5.1
80.04	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?	Yes		5.1
80.05	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?	Yes		5.1
80.06	Is the classified areas equipped with a pressure-differential monitoring system?	Yes		5.1
80.07	Does the ante-room have a line of demarcation to separate the clean side from the less clean side?	Yes		5.1
80.08	Is the ante-room entered through the less clean side, and the clean side is the area closest to the buffer area?	Yes		5.1
80.09	Is required garb worn prior to crossing the line of demarcation?	Yes		5.1
81.00	When the PEC is located in an SEC, which is an unclassified area, without an ante room or buffer area (aka SRPA), the following apply:	N/A		5.1
81.01	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA	N/A		5.1
81.02	The SRPA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.	N/A		5.1
81.03	A visible perimeter establishes the boundaries of the SRPA.	N/A		5.1

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		Observations	Notes	USP Reference(s)
81.04	Access to the SRPA is restricted to authorized personnel and required materials.	N/A		5.1
81.05	An SRPA is not located adjacent to environmental control challenges	N/A		5.1
81.06	If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (eg, Tc-99m)	N/A		5.1
82.00	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.	Yes		5.1
83.00	*Recommendation: Interlocking mechanisms are used in the pass-through(s).*	Yes		5.1
	The Radiopharmaceutical Processing Environment:			5.1
84.00	Is the PEC certified to meet ISO Class 5 or better conditions (3520 particle count (with limit ≥0.5 µm) per cubic meter) under dynamic operating conditions?	Yes		5.1
85.00	Is the airflow in the PEC unidirectional (laminar flow)?	Yes		5.1
86.00	Is "first air" at the face of the filter free from airborne particulate contamination?	Yes		5.1

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		Observations	Notes	USP Reference(s)
87.00	Is the HEPA-filtered air supplied in the direct processing area (DPA) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during operations, given the limitations added from the radiation shielding in the DPA?	Yes		6.1
88.00	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?	Yes		6.1
	Types of PECs and Placement:			6.1
89.00	Does the placement of the PEC allow for cleaning around the PEC?	Yes		6.1
90.00	**Laminar airflow workbench (LAFW):** Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?	Yes		6.1
91.00	In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized.	Yes		6.1
92.00	**Placement of PEC:** Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?	Yes		6.1

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		Observations	Notes	USP Reference(s)
92.01	If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.	N/A	There is no SRPA.	5.1
92.02	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.	Yes		5.1
93.00	Is a dynamic airflow smoke pattern test performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA?	Yes		5.1
	Air-Exchange Requirements		***Note to Inspector:*** *Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). SRPA do not have an ACPH requirement.*	
94.00	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?	Yes		
95.00	Are at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?	Yes		
96.00	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	Yes		
96.01	Does HEPA-filtered air from the PEC, added to the HVAC-supplied HEPA-filtered air, increase the total HEPA-filtered ACPH to at least 30 ACPH?	Yes		

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96.02	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?	Yes		
96.03	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?	Yes		
97.00	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?	Yes		
97.01	Are ante-rooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?	Yes		
97.02	Are the total ACPH documented on certification reports?	Yes		
	Creating Areas to Achieve Easily Cleanable Conditions			5.2
	Classified Areas:			5.2
98.00	Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate?	Yes		5.2
99.00	*Recommendation: Surfaces are resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	Yes		5.2
100.00	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices where dirt can accumulate?	Yes		5.2
101.00	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?	Yes		5.2
102.00	Are walls constructed of or covered with a durable material (eg, epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface maintained?	Yes		5.2

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		Observations	Notes	USP Reference(s)
103.00	Are panels joined together and sealed to each other and the support structure?	Yes		5.2
104.00	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?	Yes		5.2
105.00	*Recommendation: Classified areas minimize dust-collecting overhangs such as utility pipes, ledges, and windowsills.*	Yes		5.2
106.00	If overhangs or ledges are present, are they easily cleanable?	Yes		5.2
107.00	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?	Yes		5.2
108.00	Are any other penetrations through the ceiling or walls sealed?	Yes		5.2
	SRPA:			5.2
109.00	Is the SRPA and all surfaces (eg, walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	N/A		5.2
110.00	*Recommendation: Surfaces in the SRPA are smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate.*	N/A		5.2
111.00	*Recommendation: Surfaces are be resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	N/A		5.2
112.00	*Recommendation: Dust-collecting overhangs such as utility pipes, ledges, and windowsills are minimized.*	N/A		5.2
113.00	If overhangs or ledges are present, are they easily cleanable?	N/A		5.2

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		Observations	Notes	USP Reference(s)
	Water Sources:			5.3
114.00	*Recommendation: Sinks are hands-free use with a closed system of soap (ie, non-refillable).*	Yes		5.3
115.00	In facilities with an ante room and buffer room, is the sink placed inside or outside of the ante room? *Note placement, inside or outside.*	Yes	The sink is outside of the ante room.	5.3
115.01	If the sink is located outside of the ante-room, it is located in a clean space to minimize the risk of bringing in contaminants into the anteroom.	Yes	The sink is located in a clean space and well away from the anteroom door. The sink faucet showed significant signs of rust and deterioration. Please see Photo01_Nuclear115.01	5.3
115.02	If the sink is located inside the ante-room, describe where it is located.	N/A		5.3
115.03	The buffer area does not contain plumbed water sources [eg, sink(s), eyewash(es), shower(s), or floor drain(s)].	Yes		5.3
115.04	The ante room does not contain floor drain(s).	Yes		5.3
116.00	*Recommendation: If installed, sprinkler systems in classified areas are recessed & covered and are easily cleanable.*	Yes		5.3
117.00	In facilities with a SRPA design:		N/A	5.3
117.01	Is the sink accessible but located at least 1 m from the PEC and generators, if present?	N/A		5.3
117.02	Is the sink not located inside the perimeter of the SRPA?	N/A		5.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Placement and Movement of Materials:			5.4
118.00	Are only furniture, equipment, and other materials necessary permitted in the classified area or SRPA?	Yes		5.4
118.01	*Recommendation: Are furniture, equipment and materials low-shedding and easily cleaned & disinfected.*	Yes		5.4
118.02	Does the number, design, location, and manner of furniture, equipment and material installation not adversely impact environmental air quality and promote effective cleaning and disinfecting?	Yes		5.4
119.00	Are shipping carton(s) or other corrugated or uncoated cardboard not allowed in the classified area or SRPA?	Yes		5.4
120.00	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?	Yes		5.4
121.00	In a classified area, are carts not moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected?	N/A	Carts are not used to move materials in the anteroom. Carts are dedicated to the clean room only.	5.4
122.00	Are all items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-through(s), into an SRPA or into an ISO 5 PEC?	Yes		5.4

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		Observations	Notes	USP Reference(s)
	Classified Areas:			5.5
123.00	Are activities and tasks carried out within the buffer area limited to only those necessary?	Yes		5.5
124.00	Are food and drinks exposed in patient care and treatment areas not in the ante-rooms or buffer areas?	N/A	There are no patient care and treatment areas.	5.5
125.00	When processing activities require the manipulation of blood-derived or other biological material (eg, radiolabeling patient's or donor's blood cells) do the following occur?	Yes		5.5
125.01	Are the manipulations clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?	Yes		5.5
125.02	Are manipulations controlled by specific SOPs to avoid any cross-contamination?	Yes		5.5

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		Observations	Notes	USP Refererence(s)
	Remote Aseptic Processing Involving a Hot-Cell:		*Note to Inspector: In settings where tasks are carried out within the hot-cell enclosure not within an ISO-classified space by remote means (ie, no direct intervention by personnel into the ISO Class 5 space), it is not necessary for personnel to don the garbing described in this chapter for that environment to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located.*	5.6
126.00	Does a hot-cell device provide an inherent physical segregation for the ISO Class 5 aseptic processing area?	N/A	There is no hot cell in this facility.	5.6
127.00	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements of <825> for that environment?	N/A		5.6
128.00	If hand and arm incursions into the interior of the hot-cell occur causing personnel to stage the required materials and supplies, do personnel garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship?	N/A		5.6
129.00	For situations where a PEC device is located within a hot-cell, all the following apply:	N/A		5.6
129.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC?	N/A		5.6
129.02	For interventions that are outside of the PEC, do personnel garb in nonsterile gloves and a low-particulate lab coat?	N/A		5.6
129.03	If the hot-cell has failed the airflow smoke pattern test, are personnel required to garb differently?	N/A		5.6
130.00	For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, the following apply:	N/A		5.6
130.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?	N/A		5.6

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		Observations	Notes	USP Reference(s)
130.02	If a failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC.	N/A		5.6
131.00	For other hot-cell/PEC configurations and technologies that may exist, the following apply:	N/A		5.6
131.01	Does verification (either by airflow smoke pattern tests or other manufacturer specified methods) ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?	N/A		5.6
131.02	Does failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell?	N/A		5.6
	Environmental Controls:			5.7
132.00	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls? Refer to the RAM license for pressure requirements, as applicable.	Yes		5.7
133.00	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (eg, between the buffer area and ante-room)?	Yes		5.7
134.00	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?	Yes		5.7
134.01	Is the buffer area, if present, positive pressure compared to the ante-room?	Yes		5.7

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		Observations	Notes	USP Reference(s)
134.02	Is the ante-room, if present, positive pressure compared to unclassified portions of the restricted area?	Yes		5.7
135.00	Is the restricted area, in the presence of volatile or airborne radiopharmaceuticals, negative pressure compared to the unrestricted area?	Yes		5.7
136.00	Is the SRPA negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (eg, I-131 sodium iodide and Xe-133 gas)?	N/A	There is no SRPA.	5.7
	Establishing and Maintaining Pressure Differentials:			5.7
137.00	Any time a pressure differential is required, is there a pressure monitoring device?	Yes		5.7
138.00	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante- room and the general environment outside the classified area(s) or area(s)?	Yes		5.7
139.00	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?	Yes		5.7
140.00	All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.	Yes		5.7

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		Observations	Notes	USP Reference(s)
Ambient Atmosphere for Immediate Use Preparations:				5.7
141.00	All of the following requirements met in ambient atmosphere environments:	N/A		5.7
141.01	Is non-patient care space, functionally separate (not necessarily a different area) from the patient care area, such as a radiopharmaceutical handling space, or hot lab, in a hospital, clinic, or mobile coach?	N/A		5.7
141.02	Is there a designated area for medication preparation that is clean and free from clutter?	N/A		5.7
141.03	Is it a low traffic area (ie, limited number of people going in and out or moving around the area during times that radiopharmaceutical processing is being carried out)?	N/A		5.7
SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations:				5.7
142.00	Does the SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations meet the following requirements?	N/A		5.7
142.01	Area surrounding the PEC may be ambient (unclassified) atmosphere.	N/A		5.7
142.02	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals.	N/A		5.7
142.03	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals.	N/A		5.7
142.04	An area that is used to store and elute non-direct infusion radionuclide generators (eg, Tc-99m) must meet ISO Class 8 total airborne particle-count specifications.	N/A		5.7

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		Observations	Notes	USP Reference(s)
	An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector :*** *Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
143.00	ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A	The anteroom is ISO Class 7.	5.7
	An ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector :*** *Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
144.00	ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room and sterile compounding.	N/A	The anteroom is ISO Class 7.	5.7
	Hot-Cell:		***Note to Inspector :*** *Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
145.00	Hot-Cell environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A	There is no hot cell.	5.7
	Certification of PEC and Environment in which the PEC is located:			5.7
146.00	Certification of the classified areas, including the PEC, is performed initially.	Yes		5.7
147.00	Recertification is performed at least every 6 months.	Yes		5.7
148.00	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.	Yes		5.7

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		Observations	Notes	USP Reference(s)
149.00	Airflow testing is performed to determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions.	Yes		5.7
150.00	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).	Yes		5.7
151.00	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.	Yes		5.7
152.00	Smoke Visualization Studies are performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).	Yes		5.7
153.00	Are other equivalents for certifying the PEC performed and documented per facility SOPs, in cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards?	N/A		5.7
154.00	In this case, the PEC maintains the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.	N/A		5.7
	Daily Monitoring of Environment:			5.7
155.00	The temperature and humidity is monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure is monitored, each day that radiopharmaceutical handling occurs, either manually or by a continuous recording device.	Yes	This is performed manually.	5.7
156.00	Does Monitoring include the following?	Yes		5.7
156.01	*Recommendation: Relative humidity is kept at 60% or lower*	Yes		5.7

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		Observations	Notes	USP Reference(s)
156.02	Are temperature continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.03	Are relative humidity continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.04	Are excursion documented and, if applicable, appropriate corrective actions taken?	Yes		5.7
156.05	Are temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer?	Yes		5.7
156.06	Are monitoring of pressure differentials performed?	Yes		5.7
	Microbial Air and Surface Monitoring:			6
157.00	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	Yes		6
158.00	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?	Yes		6
	General Monitoring Requirements:			6.1
159.00	Is the air and surface monitoring program clearly described in the established SOPs of the facility and include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action?	Yes		6.1
159.01	Are samples obtained from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and are likely to be representative of the conditions throughout the area?	Yes		6.1

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160.00	Are personnel who operate the equipment trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling?	Yes		6.1
161.00	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?	Yes		6.1
162.00	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	Yes		6.1
163.00	Are air and surface sampling performed initially for PECs & classified areas in a facility to establish a baseline level of environmental quality?	Yes		6.1
164.00	After initial sampling, are the PECs & classified area(s) monitored according to the minimum frequencies?	Yes		6.1
165.00	Are air and surface sampling conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained?	Yes		6.1
166.00	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?	Yes		6.1
167.00	Is sampling performed in all of the following circumstances?	Yes		6.1
167.01	In conjunction with the certification of new facilities and equipment?	Yes		6.1
167.02	After any modification of facilities or equipment	Yes		6.1
167.03	In response to identified problems (eg, positive growth in sterility tests of compounded radiopharmaceuticals)?	Yes		6.1

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167.04	In response to identified trends (eg, repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)?	Yes		6.1
167.05	In response to changes that could impact the controlled area environments (eg, significant change in cleaning process or the agents involved)?	Yes		6.1
168.00	Is regular review of the sampling data performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment?	Yes		6.1
169.00	Are results reviewed in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?	Yes		6.1
170.00	Is Prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?	Yes		6.1
171.00	Is data also reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels?	Yes		6.1
	Monitoring Air Quality for Viable Airborne Particles:			6.2
	Viable Air Sampling: Timing and Locations			6.2
172.00	Volumetric active air sampling of all classified areas (eg, ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device are conducted during dynamic operating or simulated operating conditions at least every 6 months.	Yes		6.2
173.00	Does viable air sampling include the following?	Yes		6.2

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173.01	Following the manufacturer's instructions for operation of the air sampling device, including placement of media?	Yes		6.2
173.02	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled?	Yes		6.2
173.03	At the end of the sampling, retrieve the media plates/devices and cover?	Yes		6.2
173.04	Inverting the media and incubate at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air). Include sample location and date?	Yes		6.2
173.05	Incubates the inverted media at 20°–25° C for no less than 5 additional days? Examines the media plates for growth? Records the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air)? Includes sample location and date?	Yes		6.2
174.00	To shorten the overall incubation period, can two samples be collected for each sample location and incubated concurrently?	No	The two-sample procedure is not used.	6.2
175.00	Both samples could be TSA, or one sample could be TSA and the other fungal media [eg, malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. Describe samples in notes.	N/A		6.2
176.00	Each sample is incubated in a separate incubator.	N/A		6.2
177.00	One sample is incubated at 30°–35°C for no less than 48 hours and the other sample is incubated at 20°–25° C for no less than 5 days.	N/A		6.2

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178.00	Fungal media samples are incubated at 20°–25° C for no less than 5 days.	N/A		6.2
179.00	The count of the total number of discrete colonies of microorganisms are done on each sample and these results are recorded as cfu per sample.	N/A		6.2
180.00	Are the results of the sampling recorded on an environmental sampling form based on sample type (ie, viable air) and include the sample location, and sample date?	N/A		6.2
181.00	Are general microbiological growth medium that supports the growth of bacteria and fungi used (eg, TSA medium)?	Yes		6.2
182.00	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?	Yes		6.2
183.00	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?	Yes		6.2
184.00	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?	Yes	Monitoring is manual.	6.2
185.00	Are the incubators used for microbiological testing placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out?	Yes		6.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Data Evaluation and Action Levels:			6.2
186.00	Air Sampling Action Levels (cfu/cubic meter (1000L) of air per plate) are within the appropriate range: *ISO Class 5 - >1* *ISO Class 7 - >10* *ISO Class 8 - >100*	Yes		6.2
187.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.2
187.01	If two pieces of media were collected at a single location, are all recovered growth documented and action levels are applied individually to each plate/device (ie, results from each cubic meter of air sampled are compared to the action level for that area)?	N/A		6.2
188.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.2
188.01	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes		6.2
188.02	If levels measured during viable air sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.2
188.03	Is the corrective action plan documented?	Yes		6.2
188.04	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.2

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Monitoring Surfaces for Viable Particles:			6.3
189.00	Are all sampling sites and procedures described in the facility's SOP?	Yes		6.3
	Surface Sampling: Timing and Locations			6.3
190.00	Is surface sampling of all classified areas and all PECs conducted at least monthly for the detection of microbial contamination?	Yes		6.3
191.00	Is each classified area sampled?	Yes		6.3
192.00	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?	Yes		6.3
193.00	Are work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas evaluated to determine the locations that pose the greatest risk of harboring microbial contamination?	Yes		6.3
194.00	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?	Yes		6.3
195.00	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?	Yes		6.3
196.00	If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk (eg, implementation of appropriate shielding, performing the sampling at a later time or alternate day)?	Yes		6.3

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Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Sampling Procedures:			6.3
197.00	Are surface sampling devices (eg, plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?	Yes		6.3
198.00	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?	Yes		6.3
199.00	Do surface sampling devices contain general microbial growth media (eg, TSA) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents?	Yes		6.3
200.00	If used, do contact plates have a raised convex surface?	Yes		6.3
201.00	Are sterile swabs wetted with sterile water or a sterile neutralizing buffer used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces?	No		6.3
202.00	After sampling, is the sampled area thoroughly cleaned and disinfected?	Yes		6.3
203.00	Are the following procedures for surface sampling on flat surfaces used?	Yes		6.3
203.01	Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device.	Yes		6.3
203.02	If using plates, invert the plates.	Yes		6.3

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		Observations	Notes	USP Reference(s)
203.03	Incubate the surface sampling devices at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (ie, surface). Include sample location and date.	Yes		6.3
203.04	Incubate the sampling device at 20°–25° C for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (ie, surface). Include sample location and date.	Yes		6.3
204.00	Does the facility use two samples for each sampling location?	No		6.3
204.01	Are both TSA?	N/A		6.3
204.02	Is one TSA and one Fungal?	N/A		6.3
204.03	Is each sample incubated in a separate incubator?	N/A		6.3
204.04	Is one sample media incubated at 30°–35° C for no less than 48 hours?	N/A		6.3
204.05	If fungal media are used as one of the samples, is it fungal media sample incubated the at 20°–25° C or no less than 5 days?	N/A		6.3
204.06	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?	N/A		6.3
204.07	Are the results of the sampling recorded?	N/A		6.3

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Data Evaluation and Action Levels:			6.3
205.00	Surface Sampling Action Levels (cfu/device or swab) are within the appropriate range: *ISO Class 5 - >3* *ISO Class 7 - >5* *ISO Class 8 - >50*	Yes		6.3
206.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.3
206.01	If two pieces of media were collected at a single location, is all recovered growth on each documented and action levels are applied to each piece of media individually (ie, results from each sampling device are compared to the action level for that area)?	N/A		6.3
207.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.3
207.01	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?	Yes		6.3
207.02	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes		6.3
207.03	If levels measured during surface sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.3
207.04	Is the corrective action plan documented?	Yes		6.3
207.05	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.3

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting			7
208.00	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?	Yes		7
209.00	Is cleaning performed in the direction of most to least clean areas?	Yes		7
210.00	Are the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and followed by all cleaning personnel?	Yes		7
210.01	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?	Yes		7
210.02	When sterile 70% IPA is used, is it allowed to dry?	Yes		7
211.00	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?	Yes		7
212.00	Are surfaces cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step?	Yes	One-step Envirocide Surface Disinfectant Cleaner is used.	7
212.01	After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, is sterile 70% IPA applied to remove any residue?	Yes		7

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		Observations	Notes	USP Reference(s)
213.00	Does cleaning and disinfecting surfaces occur at the minimum frequencies in Table 5 or if activities are not performed daily, cleaning and disinfecting completed before initiating activities?	Yes		7
214.00	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?	Yes		7
214.01	*Recommendation: Areas shielded until radiation exposure levels lowered.*	Yes		7
214.02	Is this balance specified in SOPs (eg, trigger levels for safe cleaning)?	Yes		7
214.03	*Recommendation: The PEC is checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading redioactive contamination in the PEC.*	Yes		7
	Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the perimeter of the SRPA:			7
215.00	Does Cleaning of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occurs in the following situations?	Yes		7
215.01	Prior to performing sterile processing of radiopharmaceuticals on each day that activities are carried out, are the walls, bars, torso shield and any exposed surface of equipment inside the PEC cleaned to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
215.02	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?	Yes		7

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
216.00	Does disinfecting of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occur in the following situations?	Yes		7
216.01	Following cleaning on each day that activities are carried out, are exposed surfaces of the equipment disinfected to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
216.02	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?	Yes		7
216.03	Are new pads replaced after disinfecting or as required after spills?	Yes		7
217.00	Does Cleaning and Disinfecting occurs **DAILY** for the following?	Yes		7
217.01	PEC(s) and equipment inside the PEC(s)	Yes		7
217.02	Surface of sink(s)	Yes		7
217.03	PEC and equipment inside the PEC(s) located in a hot cell.	N/A		7
217.04	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
217.05	Work surface(s) outside the PEC	Yes		7
217.06	Floor(s)	Yes		7
218.00	Does Cleaning and Disinfecting occurs **MONTHLY** for the following?	Yes		7

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		Observations	Notes	USP Reference(s)
218.01	Ceiling(s)	Yes		7
218.02	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
218.03	Storage shelving and storage bins	Yes		7
219.00	Does Sporicidal application occurs **MONTHLY** for the following?	Yes		7
219.01	PEC(s) and equipment inside the PEC(s)	Yes		7
219.02	Surface of sink(s)	Yes		7
219.03	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
219.04	PEC and the equipment inside the PEC(s) located in a hot-cell	N/A		7
219.05	Work surface(s) outside the PEC	Yes		7
219.06	Ceiling(s)	Yes		7
219.07	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
219.08	Floor(s)	Yes		7
219.09	Storage shelving and storage bins	Yes		7

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Cleaning, Disinfecting and Sporicidal Agents:		***Note to Inspector:*** *Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties.*	7.1
220.00	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	Yes	All agents used are determined by corporate.	7.1
221.00	Are considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected?	Yes		7.1
221.01	After the disinfectant is applied on the surface to be disinfected, is the disinfectant allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed?	Yes		7.1
222.00	Is only sterile 70% IPA used in the ISO Class 5 PEC?	Yes		7.1
223.00	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?	N/A	There is no SRPA.	7.1
	Cleaning Supplies:			7.2
224.00	Are all cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders, low-lint?	Yes		7.2
225.00	*Recommendation: All cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders are disposable.*	Yes		7.2

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		Observations	Notes	USP Reference(s)
225.01	If disposable cleaning supplies are used, are they discarded after each cleaning activity?	Yes		7.2
226.00	Are reusable cleaning tools made of cleanable materials (eg, no wooden handles) and are cleaned and disinfected before and after each use?	Yes	All are stainless steel.	7.2
227.00	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?	yes		7.2
228.00	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?	yes	Only handles and heads are reusable and are made of stainless steel.	7.2
229.00	*Recommendation: Cleaning supplies and solutions used in the classified areas and SRPAs are be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs.*	Yes		7.2
230.00	Are cleaning supplies used in the classified areas and SRPAs disposed in a manner that minimizes the potential for dispersing particulates into the air (eg, with minimal agitation, away from work surfaces)?	Yes		7.2
	Cleaning and Disinfecting the PEC:			7.3
231.00	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?	Yes		7.3
232.00	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?	N/A	There is no removable work tray.	7.3

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Facility Name: RLS (USA) Inc.
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		Observations	Notes	USP Reference(s)
233.00	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?	Yes		7.3
234.00	If necessary, any particles, debris, or residue removed with an appropriate solution (eg, Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers?	Yes		7.3
235.00	Is a cleaning agent applied followed by a disinfecting agent or an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved?	Yes		7.3
236.00	Is sterile 70% IPA applied?	Yes		7.3
237.00	Are the surfaces allowed to dry completely before beginning activities?	Yes		7.3
238.00	Is the PEC wiped with a sporicidal agent at least monthly?	Yes		7.3
	Disinfecting Supplies for Classified Areas and SRPAs:			7.4
239.00	Are shipping carton(s) or other corrugated or uncoated cardboard prohibited in the classified area (eg, clean side of ante-room) or within the perimeter of the SRPA?	Yes		7.4
240.00	Before items are introduced into a classified area or SRPA, are they wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers?	Yes	Oxivir 1, a disinfectant cleaner is used, followed by sterile 70% IPA.	7.4

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Facility Name: RLS (USA) Inc.
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		Observations	Notes	USP Reference(s)
241.00	After the sporicidal or sterile disinfectant is applied onto the surface, is the agent allowed to dwell on the surface for the minimum contact time specified by the manufacturer?	Yes		7.4
241.01	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?	Yes		7.4
242.00	Are any items to be transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant (eg, sterile 70% IPA)?	Yes		7.4
243.00	If radiopharmaceuticals are being processed by remote means in a hot-cell, the opening of sterile packages (eg, syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area.	[redacted]	N/A	7.4
243.01	In this case, are the syringes opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle?	N/A		7.4
	Disinfecting Critical Sites:			7.5
244.00	Are critical sites (eg, vial stoppers) wiped with sterile 70% IPA? Note: If the vial shield top is then closed, the septum is disinfected again with sterile 70% IPA prior to another needle puncture.	Yes		7.5
245.00	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?	Yes		7.5
246.00	Is the sterile 70% IPA allowed to dry before piercing critical sites?	Yes		7.5
247.00	Is the septum wiped with sterile 70% IPA frequently whenever multiple punctures are occurring (eg, removing several individual doses from a multiple-dose container)?	Yes		7.5

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Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting Items from Patient Care Area:			7.6
248.00	Is radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area (eg, buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention Guidelines 1 classified as noncritical equipment requiring low-risk disinfection?	N/A	There is no patient care area.	7.6
249.00	Are syringes that have been used in a patient care area not brought back into the classified area (eg, buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (eg, sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA?	N/A		7.6
250.00	Is equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs considered mixed waste (eg, syringe shields and syringe carrying containers)?	N/A		7.6
250.01	Is this equipment cleaned and disinfected through actions regulated by the facility's SOPs?	N/A		7.6
250.02	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?	N/A		7.6
	Assigning BUDs:			8
251.00	Does the pharmacy have policies and SOPs appropriate to the assignment of BUD and maintain documentation of applicable study results and calculations?	Yes	All BUDs are assigned by corporate.	8
252.00	*Recommendation: Studies of radiolabeling efficiency and radiochemical stability employ quality control (QC) testing methods described in the manufacturer's package insert, USP monographs and general chapters, or other equivalent testing methods and are sufficiently rigorous to allow statistical confidence in the results.*	Yes		8

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
253.00	Does the pharmacy have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?	Yes		8
254.00	*Recommendation: Policies and SOPs are also in place to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability.*	Yes		8
255.00	Does the individual responsible for the manipulation assign the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature?	No	All BUDs are assigned by corporate.	8
256.00	Preparation Conditions for Sterile Radiopharmaceuticals: *Describe condition used at the pharmacy in notes section (Table 7).*	[redacted]	Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using sterile components are completed in an ISO Class 5 PEC with an ISO Class 7 buffer room and anteroom. Radiolabeled blood components are manipulated in an ISO Class 5 BSC with an ISO Class 7 buffer room and anteroom.	8
257.00	For compounded preparations (sterile and nonsterile) plus preparations with minor deviations, is BUD dependent on maintenance of quality and purity including radiochemical purity, radionuclidic purity and other applicable parameters as specified in individual monographs or as clinically appropriate?	Yes		8
258.00	Assignment of BUD for a radiopharmaceutical considers several factors, as appropriate. Issues of concern include all but are not limited to the following:	Yes		8
259.00	*Recommendation: The assigned BUD does not exceed the sterility-related times listed in Table 7 unless a longer time is justified by Sterility tests per <71>.*	Yes		8
260.00	Radiochemical Purity - Is the assigned BUD based on stability studies in which these variables are controlled and are representative of the conditions of actual use?	Yes		8
261.00	*Recommendation: For factors that allow a range of values (eg, storage temperature, quantity of radioactivity, radioactivity concentration), studies are conducted at the extreme of the ranges.*	Yes		8

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
262.00	Radionuclidic purity - USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration.	Yes		8
263.00	Are calculations of radionuclidic purity at future times necessary to ensure compliance throughout the assigned BUD?	Yes		8
264.00	Age of the generator eluate - Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits take into account the build-up of Tc-99 and peroxides over time.	Yes		8
265.00	Number of particles - For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. Calculation of the number of MAA particles in the patient dose is conducted to ensure compliance with the prescribed particle range throughout the assigned BUD.	Yes		8
266.00	Specific Activity - For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake. In such situations, the assigned BUD ensures that the patient dose contains no more than the specified mass.	Yes		8
267.00	Container Type – The assigned BUD is determined in the proper storage container.	Yes		8
268.00	*Cell Viability – Recommendation: The assigned BUD is as short as circumstances reasonably allow so as to maximize cell viability.*	yes		8
269.00	In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s).	yes		8
270.00	In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation.	Yes		8
271.00	A radiopharmaceutical may not exceed the shortest BUD of any of its components.	Yes		8

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
Documentation:				9
272.00	Are applicable records (hard-copy or electronic), including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals?	Yes		9
273.00	Do such records include all but are not limited to the following?	Yes		9
273.01	Personnel training and testing including visual assessment of aseptic technique competency	Yes		9
273.02	Validation	Yes		9
273.03	Garbing	Yes		9
273.04	Hand hygiene	Yes		9
273.05	Equipment/environment cleaning and disinfecting	Yes		9
273.06	Gloved fingertip and thumb sampling	Yes		9
273.07	Media fill evaluation initially	Yes		9
273.08	Media fill follow up testing at specified intervals	Yes		9
273.09	Equipment maintenance and cleaning/disinfecting	Yes		9
273.10	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations	Yes		9
273.11	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding	Yes		9

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		Observations	Notes	USP Reference(s)
273.12	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature	Yes		9
273.13	Investigations and corrective actions and tracking of events to closure.	Yes		9
274.00	Do Testing and Monitoring of environmental controls include the following?	Yes		9
274.01	ISO classification	Yes		9
274.02	ACPH	Yes		9
274.03	Pressure differentials	Yes		9
274.04	Temperature	Yes		9
274.05	*Recommendation: Humidity*	Yes		9
274.06	Viable air	Yes		9
274.07	Viable surface	Yes		9
274.08	Total particle test results	Yes		9
	Master Formulation Record:			9.1
275.00	Preparations with minor deviations or compounding have a MFR. *Note: A MFR is not required for a preparation following the manufacturer's instructions.*	Yes		9.1
276.00	Do the elements of the MFR include at a minimum the following?	Yes		9.1
276.01	Name of the radiopharmaceutical	Yes		9.1

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
276.02	Name or ID number, pharmacy, strength, purity, quality, and quantity of ingredients with validated documentation (eg, CoA)	Yes		9.1
276.03	Detailed procedure (eg, heating, components, incubation time)	Yes		9.1
276.04	Range of radioactivity	Yes		9.1
276.05	Range of volume	Yes		9.1
276.06	Equipment to be used	Yes		9.1
276.07	PEC and SEC to be used, if applicable	Yes		9.1
276.08	Quality control tests to be performed for final release of the radiopharmaceutical (eg, radiochemical purity, pH)	Yes		9.1
276.09	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits	N/A		9.1
276.10	Trained Personnel	Yes		9.1
276.11	Garbing procedure, if different than standard procedure	Yes		9.1
276.12	Container(s)	Yes		9.1
276.13	Reference source of the BUD assignment and storage conditions	Yes		9.1
	Records for Preparation with Minor Deviations/Compounding:			9.2
277.00	Does the record for preparation with minor deviation or compounding includes at a minimum, as applicable, the following?	Yes		9.2
277.01	Name of the radiopharmaceutical	Yes		9.2
277.02	Physical form (eg capsule or solution)	Yes		9.2

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
277.03	Name and quantity of ingredients including calibration time for radioactive ingredients (eg, 100 mCi Tc 99m sodium pertechnetate @ 1300)	Yes		9.2
277.04	Total volume	Yes		9.2
277.05	Reference to the MFR	Yes		9.2
277.06	Any deviation from the MFR, if applicable	Yes		9.2
277.07	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components	Yes		9.2
277.08	Name of the person who prepared and name of the supervising personnel (eg, ANP)	Yes		9.2
277.09	Date and time of preparation	Yes		9.2
277.10	Assigned internal identification number (eg, lot number)	Yes		9.2
277.11	Unique reference [eg, prescription, order number(s)]	Yes		9.2
277.12	Assigned BUD and storage requirements	Yes		9.2
277.13	Documentation of QC results	Yes		9.2
	Preparation			10
278.00	The individual responsible for preparing the radiopharmaceutical(s) ensures that the final preparation complies with quality and purity specifications throughout the assigned BUD.	Yes		10
279.00	Do the quality and purity specifications include, as appropriate for the preparation, the following?	Yes		10
279.01	Radionuclidic purity	Yes		10

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		Observations	Notes	USP Reference(s)
279.02	Radiochemical purity	Yes		10
279.03	Chemical purity	Yes		10
279.04	Physical and chemical properties	Yes		10
	Preparation Following Manufacturer Instructions			10.1
	Nonsterile Preparations			10.1
280.00	For nonsterile preparations, manufacturer preparation instructions are followed (eg, I-131 NaI capsules or solution), taking into account appropriate radiation safety considerations and environmental controls, if applicable (eg, negative air pressure area, chemical fume hood, activated charcoal filters when handling a potentially volatile radionuclide).	Yes		10.1
281.00	*Recommendation: The area is cleaned and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical(s).*	Yes		10.1
282.00	*Recommendation: There is a documented process for activities (eg, cleaning) between the preparation cycles of different nonsterile products, to decrease the likelihood of contamination from other prepared products.*	Yes		10.1
	Sterile Preparations			10.1
283.00	For sterile preparations (including intravascular devices), manufacturer preparation instructions are followed, taking into account appropriate radiation safety considerations, appropriate environmental controls, and aseptic handling practices to maintain sterility.	Yes		10.1
284.00	The minimum environmental standard for the preparation of sterile radiopharmaceuticals beyond immediate-use is within an ISO Classified area or device.	Yes		10.1

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Nuclear Pharmacy Inspection

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Preparation with Minor Deviations			10.2
285.00	In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA approved labeling.	Yes		10.2
285.01	Deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions.	Yes		10.2
286.00	The minor deviations utilized require appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or are supported by appropriate peer-reviewed publications.	Yes		10.2
287.00	Do the pharmacy radiopharmaceutical preparations with minor deviations include all of the following when applicable?	Yes		10.2
287.01	Altering the quantity of radioactivity or volume added to the vial	Yes		10.2
287.02	Changes in step-by-step operations (eg, dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)	Yes		10.2
287.03	Using alternative devices or equipment (eg, a heating block rather than a hot water bath, using a different sized needle, different shielding materials)	Yes		10.2
287.04	Using QC test methods other than those described in the product labeling (eg, radiochemical purity)	Yes		10.2
287.05	Filtering Tc-99m sulfur colloid	Yes		10.2
287.06	Other, (if so, describe in the notes)	No		10.2

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Preparation of Radiolabeled Blood Components		***Note to Inspector:** Handling blood and radiolabeling of blood components requires special attention to biological risks and need to be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered.*	10.3
288.00	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.	Yes		10.3
289.00	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.	Yes	Equipment and supplies are never shared.	10.3
290.00	Do special precautions when radiolabeling of blood components for non-immediate use include the following?	Yes		10.3
290.01	There is complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs are in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions.	Yes		10.3
290.02	One radiolabeling procedure per PEC at a time. Blood products from more than one patient are never manipulated at the same workstation at the same time. Each area has dedicated supplies, equipment, and waste disposal to eliminate sharing of these items or overlap in pathways.	Yes		10.3
290.03	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.	Yes		10.3
290.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator is used or the dose calibrator dipper and liner is cleaned and disinfected following the radioassay.	N/A	Dose calibrators are dedicated.	10.3

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		Observations	Notes	USP Reference(s)
290.05	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.	Yes		10.3
290.06	Dedicated (per each radiolabeling procedure) consumable products (eg, 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure.	Yes		10.3
290.07	All tubes and syringes in contact with the patient's blood components are clearly labeled with the patient's name and at least one additional identifier (eg, date of birth, medical record number, barcode).	Yes	A patient barcode is used in addition to the name.	10.3
290.08	Dedicated syringe shields and vial shields.	Yes		10.3
290.09	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.	Yes		10.3
290.10	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.	Yes		10.3
290.11	Cleaning and disinfection of all reusable equipment and components (eg, BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) is done after each radiolabeling procedure prior to any further use. Policies and SOPs address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient.	Yes		10.3
290.12	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.	Yes		10.3

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e-Profile ID: 1803196
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		Observations	Notes	USP Reference(s)
Preparation of Radiolabeled Red Blood Cells for Immediate Use				10.4
291.00	Is In vitro red blood cell labeling prepared with the following conditions?	N/A	There are no immediate use radiolabeled red blood cells.	10.4
291.01	A dedicated space for blood handling is designated through the entirety of the blood radiolabeling process. This area is free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection.	N/A		10.4
291.02	Only one radiolabeling procedure is performed at a time or there are documented processes that maintain the integrity of samples and environment.	N/A		10.4
291.03	Dedicated equipment is used for blood radiolabeling procedure (eg, L-block, syringe shield, vial shield, forceps, needle recapper).	N/A		10.4
291.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product is used to decontaminate the dipper and liner of the dose calibrator following the radioassay	N/A		10.4
291.05	A cleaning and disinfecting procedure with an appropriate agent(s) is used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded	N/A		10.4
291.06	All requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations are followed.	N/A		10.4
291.07	The start time of the preparation begins with the initial container puncture or the exposure of a critical site (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.	N/A		10.4
291.08	The compounded product has a BUD of 1 hour	N/A		10.4

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e-Profile ID: 1803196
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		Observations	Notes	USP Reference(s)
	Compounding		***Note to Inspector:*** *The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides.*	11
292.00	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.	Yes		11
292.01	The compounding record provides traceability for components and person(s) involved.	Yes		11
293.00	All sterile compounding, using aseptic technique, is performed in an ISO 5 PEC. Compounding employees are using appropriate aseptic technique. May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). ***When applicable, Compounding MUST be observed****, if compounding is not being performed at the time of survey mark item as "No".*	Yes		11
293.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization.*	[redacted]	N/A	11
294.00	Compounding is not be performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness, unless part of an institutional review board approved investigational study.	Yes		11
295.00	Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals are not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.	Yes		11

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
Compounding Nonsterile Radiopharmaceuticals			***Note to Inspector:*** *Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical.*	**11.1**
296.00	Areas designated for nonsterile compounding are cleaned, uncluttered and separated from areas designated for sterile radiopharmaceuticals.	Yes		**11.1**
297.00	*Recommendation: Compounding takes into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable.*	Yes		**11.1**
298.00	The placement of equipment and materials are designed to prevent cross-contamination.	Yes		**11.1**
299.00	When feasible, disposable material is used to reduce the chance of cross-contamination.	Yes		**11.1**
300.00	Each compound has a unique MFR.	Yes		**11.1**
301.00	The preparation information is documented on a compounding record.	Yes		**11.1**
302.00	The MFR details the selection of all components.	Yes		**11.1**
303.00	**The ingredients obtained from sources in this preferential order:** FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use.	Yes	Only FDA-approved products are used.	**11.1**
304.00	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (eg, CoA).	Yes		**11.1**

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
305.00	Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means.	N/A	There are no meal components compounded.	11.1
306.00	A BUD for the compounded radiopharmaceutical is validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.	Yes		11.1
306.01	A BUD cannot be extended past the labeled expiration date of any component in the compound.	Yes		11.1
306.02	If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical does not exceed the shortest remaining BUD of any of those components.	N/A		11.1
	Sterile Compounding		***Note to Inspector:*** *Kit-splitting (also referred to as "fractionation") may be used to meet patient need.*	11.2
307.00	Do personnel responsible for compounding consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD?	Yes		11.2
308.00	Do the compounding activities involve the addition of a conventionally manufactured drug product (eg, Ascorbic Acid Injection, Lidocaine Hydrochloride Injection, Sodium Bicarbonate Injection) approved by the appropriate regulatory agency to a radiopharmaceutical?	Yes	Lidocaine HCl injection may be used.	11.2
309.00	Does the pharmacy split conventionally marketed kits?	No		11.2
310.00	Do personnel responsible consider all possible interactions of kit components with these other containers (eg, container walls, closures), as well as possible alterations in stability (eg, physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD?	Yes	Corporate assigns all BUDs.	11.2
310.01	Systematic QC testing is performed to validate the appropriateness of a particular BUD.	N/A		11.2

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Verified Pharmacy Program® Inspection Form

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Nuclear Pharmacy Inspection

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Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
Sterile Compounding Using Nonsterile Drug Substance or Components				**11.3**
311.00	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.	No	There is no nonsterile to sterile compounding performed.	**11.3**
311.01	If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (eg, filtration with bubble point testing) and testing described in <85> is performed. Record calibration date of the bubble test pressure gauge, as applicable.	N/A		**11.3**
312.00	The designated person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity.	N/A		**11.3**
313.00	The designated person considers all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.	N/A		**11.3**
313.01	Testing to validate the appropriateness of a particular BUD may be required.	N/A		**11.3**
314.00	If compounding involves a bulk drug substance, the radiopharmaceutical complies with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product.	N/A		**11.3**
314.01	A bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical.	N/A		**11.3**
315.00	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.	N/A		**11.3**

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		Observations	Notes	USP Reference(s)
316.00	If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients comply with standards of an applicable USP or NF monograph, if one exists.	N/A		11.3
317.00	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	N/A		11.3
	Dispensing and Radioassay		*Note to Inspector: Dispensing refers to the manipulations necessary to transfer the prescribed or ordered amount of radiopharmaceutical into the final container (eg, syringe or vial).*	12.1
318.00	Labeling of the final patient-ready dose or ordered amount of a radiopharmaceutical is also a component of the dispensing process.	Yes		12.1
319.00	Except for an unopened manufacturer container, the final dose or ordered amount is radioassayed (ie, in a dose calibrator).	Yes		12.1
320.00	*Recommendation: The measured activity is mathematically corrected for radioactive decay to the time of scheduled administration (calibration time).*	Yes		12.1
321.00	The activity at calibration time is always be within federal, state, and local variance limits.	Yes		12.1
	Labeling			12.2
322.00	*Recommendation: All personnel distributing and/or dispensing radiopharmaceuticals verify that any labeling is in compliance with regulatory agencies.*	Yes		12.2
323.00	Is the inner container (eg syringe, vial) labeled with all of the following?	Yes		12.2
323.01	Standard radiation symbol	Yes		12.2
323.02	The words "Caution—Radioactive Material"	Yes		12.2

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Facility Name: RLS (USA) Inc.
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		Observations	Notes	USP Reference(s)
323.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
323.04	Radionuclide and chemical form (generic name)	Yes		12.2
323.05	Radioactivity at the date and time of calibration	Yes		12.2
324.00	Is the outer shielding (eg, syringe or vial shielding) labeled with all the following?	Yes		12.2
324.01	Standard radiation symbol	Yes		12.2
324.02	The words "Caution—Radioactive Material"	Yes		12.2
324.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
324.04	The radionuclide and chemical form (generic name)	Yes		12.2
324.05	Radioactivity with units at time of calibration and the calibration time	Yes		12.2
324.06	Volume or number of units (eg, 2 capsules), as applicable	Yes		12.2
324.07	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (eg, refrigeration, resuspension)	Yes		12.2
324.08	Route of administration	Yes		12.2

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Nuclear Pharmacy Inspection

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Direct Infusion Systems			12.3
325.00	Do the operations of the direct infusion systems follow the "Instructions for Use" in the device labeling?	N/A	There are no direct infusion systems.	12.3
326.00	Are each of the following parameters considered by the operator of the system?	N/A		12.3
326.01	Setup attachment or needle-puncture should be performed in a defined environment	N/A		12.3
326.02	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems	N/A		12.3
326.03	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag is labeled with the date and time of puncture and the BUD	N/A		12.3
326.04	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial is disinfected with sterile 70% IPA prior to puncturing the vial with the needle	N/A		12.3
326.05	The septum of any vial and the ports of any diluent bag is wiped with sterile 70% IPA prior to puncturing	N/A		12.3
326.06	When puncturing the vial in ambient air, it is only punctured once	N/A		12.3
326.07	If there are problems with the infusion device, no sterile container(s) associated with the system is repunctured or transferred to a PEC for further manipulations and the container, with contents, is discarded	N/A		12.3

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Facility Name: RLS (USA) Inc.
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		Observations	Notes	USP Reference(s)
	Transporting Generators Between Facilities			12.4
327.00	Are the following standards followed if transporting generators between facilities?	N/A	There is no transportation of generators.	12.4
327.01	The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors	N/A		12.4
327.02	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system	N/A		12.4
	Repackaging			13
328.00	If the facility repackages, are the following applicable?	Yes		13
328.01	Removes conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.	No		13
328.02	Places the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients	Yes		13
329.00	Does the facility repackage nonsterile radiopharmaceuticals (eg, I-131 sodium iodide oral capsules)?	Yes		13
330.00	Does the facility repackage sterile radiopharmaceuticals (eg, thallous chloride Tl 201 injection)?	Yes	Indium-111 DTPA may be repackaged.	13
331.00	Unopened manufacturer dosage units (eg, capsules, Xe-133 vials) are not radioassayed.	No		13

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		Observations	Notes	USP Reference(s)
332.00	The repackaged radiopharmaceutical is radioassayed (ie, in a dose calibrator), if it is not an unopened manufacturer dosage unit.	Yes		13
333.00	*Recommendation: The inner container is labeled with all of the following:*	Yes		13
333.01	*Standard radiation symbol*	Yes		13
333.02	*The words "Caution—Radioactive Material"*	Yes		13
333.03	*The radionuclide and chemical form (generic name)*	Yes		13
333.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13
334.00	*Recommendation: The outer container is labeled with all of the following:*	Yes		13
334.01	*Standard radiation symbol*	Yes		13
334.02	*The words "Caution—Radioactive Material"*	Yes		13
334.03	*The radionuclide and chemical form (generic name)*	Yes		13
334.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13
334.05	*Volume, or number of units (eg, capsules), as applicable*	Yes		13
334.06	*Product expiration or BUD, as applicable*	Yes		13
334.07	*Special storage and handling instructions*	Yes		13

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Quality Assurance and Quality Control			14
335.00	QA and QC programs are formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.	Yes		14
336.00	A designated person ensures that the facility has formal, written QA and QC programs. *List this person in the notes.*	Yes	Janice Swett, a staff pharmacist, is the lead person for QA and QC and reports to Otha Bright, the designated person and PIC.	14
337.00	Do QA and QC programs establish a system which include of all of the following?	Yes		14
337.01	Adherence to procedures	Yes		14
337.02	Prevention and detection of errors and other quality problems	Yes		14
337.03	Evaluation of complaints and adverse events	Yes		14
337.05	Appropriate investigations and corrective actions	Yes		14
338.00	The SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.	Yes		14
339.00	The overall QA and QC program is reviewed at least once every 12 months by the designated person. *List last date of review in notes.*	No	The PIC stated he reviews the QA and QC program monthly but was not able to find the last review.	14
340.00	The results of the review are documented, and appropriate corrective action taken, if needed.	No	The PIC stated that the program is reviewed monthly but there has been no documentation of the review.	14

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals			14.1
341.00	If a radiopharmaceutical is dispensed or administered before the results of release testing are known, does the facility have all of the following SOPs in place?	N/A	Radionuclidic potency and purity testing are performed before release. There is no other testing required.	14.1
341.01	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes)	N/A		14.1
341.02	Determine whether a recall is necessary	N/A		14.1
342.00	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain all of the following procedures?	Yes		14.1
342.01	Determine the severity of the problem and the urgency for the implementation and completion of the recall	Yes		14.1
342.02	Determine the distribution of any affected radiopharmaceutical, including the date and quantity	Yes		14.1
342.03	Identify patients who have received the radiopharmaceutical	Yes		14.1
342.04	Outline the disposition and reconciliation of the recalled radiopharmaceutical	Yes		14.1
343.00	Does the facility document the implementation of the recall procedures?	Yes		14.1
344.00	Is the recall is reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (eg, state board of pharmacy, state health department)?	Yes		14.1

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		Observations	Notes	USP Reference(s)
	Complaint Handling			14.2
345.00	Has the nuclear pharmacy developed and implemented SOPs for handling complaints? Note: Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.	Yes		14.2
346.00	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?	Yes		14.2
346.01	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?	Yes		14.2
346.02	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?	Yes		14.2
346.03	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?	Yes		14.2
346.04	Does the investigation consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected?	Yes		14.2
347.00	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint (eg, e-mail, telephone, mail)?	Yes	Records of complaints are maintained electronically.	14.2
348.00	Does the record contain all of the following?	Yes		14.2
348.01	The name of the complainant	Yes		14.2
348.02	The date the complaint was received	Yes		14.2
348.03	The nature of the complaint	Yes		14.2
348.04	The response to the complaint	Yes		14.2

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		Observations	Notes	USP Reference(s)
348.05	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (eg, prescription, order, or lot number).	Yes		14.2
349.00	Does the record also include the findings of any investigation and any follow-up?	Yes		14.2
350.00	Are records of complaints easily retrievable for review and evaluation for possible trends?	Yes		14.2
351.00	Are records retained in accordance with the record keeping requirements?	Yes		14.2
352.00	Is a radiopharmaceutical that is returned in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations?	Yes		14.2
	Adverse Event Reporting			14.3
353.00	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations?	Yes		14.3
354.00	*Recommendation: Adverse events potentially associated with the quality of the radiopharmaceutical preparation are reported to the applicable jurisdictional regulatory body (eg, state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).*	Yes		14.3

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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Acronym	Definition
ACPH	Air changes per hour
ALARA	As low as reasonably achievable
ANDA	Abbreviated new drug application
ANP	Authorized nuclear pharmacist
AU	Authorized user
BLA	Biologics license application
BSC	Biological safety cabinet
BUD	Beyond-use date
CETA	Controlled Environment Testing Association
cfu	Colony-forming unit
CoA	Certificate of analysis
DPA	Direct processing area
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IND	Investigational new drug
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFW	Laminar airflow workbench
MAA	Macroaggregated albumin
MEA	Malt extract agar
MFR	Master Formulation Record
NDA	New drug application
NRC	Nuclear Regulatory Commission
PEC	Primary engineering control
PET	Positron emission tomography
RAM	Radioactive material
RDRC	Radioactive drug research committee
RH	Relative humidity
SDA	Sabouraud dextrose agar
SEC	Secondary engineering control
SOP	Standard operating procedure
SRPA	Segregated radiopharmaceutical processing area
TSA	Trypticase soy agar

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.

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Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor

Glossary

Administration:	The direct and immediate application of a radiopharmaceutical to a patient by injecting, infusing, ingesting, or otherwise providing a radiopharmaceutical in its final form.
Airlock:	A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas.
Ante-room:	An ISO Class 8 or cleaner area with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition area between the unclassified area in a facility and the classified buffer area.
Aseptic processing or preparation:	A process by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility.
Aseptic technique:	Methods utilized during the processing of radiopharmaceuticals to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at a nearly irreducible number.
As low as (is) reasonably achievable (ALARA):	The effort to maintain exposures to ionizing radiation as far below the dose limits as practical. These efforts should be consistent with the purpose for which the licensed activity is undertaken, in relation to utilization of licensed materials in the public interest. Limiting exposure time, using adequate shielding, and maintaining the most distance possible from all radioactive sources (i.e., time, distance, shielding) are the basic principles for successfully following ALARA guidelines.
Authorized nuclear pharmacist (ANP):	A pharmacist recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as having met training and experience requirements for the practice of nuclear pharmacy.
Authorized user (AU):	A physician recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as meeting training and experience requirements for specified medical uses of radioactive material.
Beyond-use date (BUD):	The assigned date and time beyond which the radiopharmaceutical must not be administered.
Biological safety cabinet (BSC) Class II:	A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. The BSC is designed to provide worker protection from exposure to biohazardous material and to provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals.
Blood components:	Any constituent of blood that is separated by physical or mechanical means (eg, red cells, white cells, platelets)
Buffer area:	An ISO Class 8 or cleaner area with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer area may only be accessed through the ante-room.
Chemical purity:	The fraction of the total chemical species present in the radiopharmaceutical as the specified chemical component(s). A chemical impurity is the presence of an unwanted non-radioactive chemical.
Classified area:	An area that maintains an air quality classification based on the ISO guidelines (i.e., ante-room, buffer area). See ISO class.
Cleaning agent:	A material for the removal of residues (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Compounding:	The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides. See Preparation with minor deviations.
Container–closure system:	The packaging components that contain or come in contact with the radiopharmaceutical and maintain the integrity of the radiopharmaceutical contained within. Examples include (but are not limited to) vials, tubes and syringes.

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Critical site:	A location that includes any component or fluid pathway surface (eg, vial septa, injection ports) or openings (eg, needle hubs) that, when exposed is at risk for contamination by direct contact with air (eg, ambient area or HEPA-filtered), moisture (eg, oral and mucosal secretions), or touch.
Designated person:	One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.
Direct infusion system:	An FDA-cleared medical device used to dispense and/or administer radiopharmaceuticals to multiple patients. The standards of this chapter pertain to devices with ambient air that lack and ISO Class 5 environment.
Direct processing area (DPA):	An area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant:	A chemical or physical agent used on inanimate surfaces and objects to destroy microbiological contamination (eg, fungi, viruses, and bacteria) when used in the appropriate concentrations and for the appropriate contact times. Sporicidal disinfectant agents are considered a special class of disinfectants that also are effective against bacterial endospores and fungal spores.
Dispensing:	The manipulation or labeling of a radiopharmaceutical to render it in its final form for administration, typically obtained from a single-dose or multiple-dose container (eg, withdrawing a volume of finished product or preparation from a vial into a syringe). Dispensing is performed under the supervision of a physician or pharmacist and for radiopharmaceuticals includes dilution with an appropriate diluent or adjusting the activity in an individual dosage.
Dose pooling:	The combining of doses from two or more syringes to meet one patient's need, also see "repackaging".
Dose splitting:	The splitting of a patient-ready unit dose for use with more than one patient.
Dynamic operating conditions:	Conditions in the SRPA or classified area in which operating personnel are present and performing actual or simulated activities. The PEC should contain equipment and materials regularly used for radiopharmaceutical processing (eg, low-lint absorbent pads, dose calibrator, syringe shields).
Expiration date:	For conventionally manufactured radiopharmaceuticals, the specified date (and time) beyond which the product must not be administered. The expiration date is determined by the manufacturer.
First air:	The air exiting the HEPA filter in a unidirectional air stream.
Garb:	Gloves, gowns, shoe covers, head (covers ears and all hair) and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of microbiological contamination to radiopharmaceuticals.
High efficiency particulate air (HEPA) filtration:	Using a tested and certified air filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter from the air passing through it.
Hot-cell:	A device used for the shielding and containment of radioactive materials. The shielding material(s) (eg, lead) is generally incorporated into the structure of the unit itself. Radiopharmaceutical personnel carry out the majority of the tasks within the hot-cell from the exterior of the unit. This is accomplished by the use of remote manipulation systems (eg, manipulator arms, automated dispensing system) of various designs. Numerous air quality configurations of the hot-cell may exist, including integrated HEPA filtration systems to render all or a specified portion (DPA) of the device capable of certifying to a controlled ISO Class 5 environment. In other situations, the hot-cell offers only radiation protection and a laminar flow PEC, capable of achieving an ISO Class 5 environment, is placed within the enclosure to allow for safe aseptic manipulations. A hot-cell may also be referred to by other designations (eg, shielded isolator with laminar flow, PET dispensing station, manipulator hot-cell, shielded isolators for dispensing, radiopharmaceutical dispensing isolator).
Hot lab:	Unclassified radiopharmaceutical processing area located within a hospital or clinical site that is only appropriate for immediate use radiopharmaceuticals if there is not an ISO 5 PEC within SRPA located within the area.
Immediate use:	A preparation (including preparations with minor deviations) and/or dispensing of a sterile radiopharmaceutical that is limited for a single patient. Only sterile conventionally manufactured drug products (eg, NDA, ANDA) or drugs produced under an approved IND or RDRC protocol may be used. Administration must begin within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.
Individual dose (unit dose):	A radiopharmaceutical in its final form ready for administration (eg, capsule, sterile solution in a syringe) consisting of the amount (dose) prescribed, ordered, or other intended for an individual patient or research subject.
Inverse square law:	The specified physical quantity or intensity of a radiation emission is inversely proportional to the square of the distance from the source of the emission.
ISO class:	A quality classification from the International Organization for Standardization based on quantity and size of particles per volume of air.
Kit:	Conventionally manufactured package containing all ingredients required to prepare a radiopharmaceutical with the exception of the radionuclide.

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Kit-splitting (fractionation):	The act of dividing the contents of a kit vial and transferring aliquots into other containers for storage and subsequent radiolabeling.
Ligand:	An ion or molecule that incorporates a metal atom to form a coordination complex.
Line of demarcation:	A visible line on the floor that separates the clean and less clean sides of the ante-room.
Low-lint wiper:	A wiper exhibiting few, if any, fibers or other particulates, visible without magnification, which are separate from, or easily removed from, the wiper material in a dry condition.
Master Formulation Record (MFR):	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished preparations as well as the processing instructions, including the in-process controls.
Media-fill test:	A simulation used to qualify processes and personnel engaged in sterile radiopharmaceutical processing to ensure that the processes and personnel are able to prepare radiopharmaceuticals without microbiological contamination. Molar mass: The measured mass that is attained from a molar amount of a given substance (eg, element, compound).
Molar mass:	The measured mass that is attained from a molar amount of a given substance (eg, element, compound). It is generally expressed with units such as g/mol and kg/mol.
Multiple-dose container:	A container of a radiopharmaceutical for administration that is designed to contain more than one patient dose of the radiopharmaceutical.
Negative-pressure area:	An area that is maintained at lower pressure than the adjacent spaces, and therefore the net airflow is into the area. This area is appropriate for volatile or gaseous radionuclides and radiopharmaceuticals (eg, I-131 NaI, N-13 ammonia) and intended to lend a measure of protection for the radiation workers and the general public.
One-step disinfectant cleaner:	A product with an EPA-registered claim (or equivalent) that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Pass-through:	An enclosure with sealed doors on both sides to ensure that both doors are not opened at the same time. The pass-through is positioned between two spaces creating an airlock for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter:	A visible demarcation on the floor that defines the boundaries of the SRPA.
Positive-pressure area:	An area that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the area.
Preparation:	The act of combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.
Preparation with minor deviations:	The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (eg, dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (eg, a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods.
Primary engineering control (PEC):	A device or zone that provides an ISO Class 5 air quality environment for sterile processing.
Pyrogen:	A substance that induces a febrile reaction in a patient.
Quality assurance (QA):	The system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards.
Quality control (QC):	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical.
Radioactive materials (RAM) license:	A document(s) issued by the US NRC or an Agreement State agency that authorizes various activities involving the use of radioactive materials. These uses can include possession, research and development, distribution, medical use, and other purposes not included in this list. Only those activities specifically authorized are allowed.
Radioassay:	Measurement of the quantity of radioactivity present in a container using a suitable and calibrated instrument, such as a well-type ionization chamber (i.e., dose calibrator).
Radiochemical purity:	The ratio, expressed as a percentage, of the radioactivity of the intended active radiopharmaceutical ingredient to the total radioactivity of all radioactive ingredients and impurities present in the radiopharmaceutical preparation (see Radioactivity <821>).
Radionuclidic purity:	The ratio, expressed as a percentage, of the radioactivity of the intended radionuclide to the total radioactivity of all radionuclides in the radiopharmaceutical preparation (see <821>).

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Radiopharmaceutical (radiopharmaceutical preparation/radioactive drug):	(See <821>.) A finished dosage form that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms "radiopharmaceutical" and "radioactive drug" are commonly used interchangeably.
Repackaging:	The act of removing a conventionally manufactured radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers (eg, vials) of the same finished drug product into one container, as long as the container does not include other ingredients. Radiopharmaceutical manipulation in any other way, including reconstitution, dilution, mixing, or combination with another ingredient, is not considered repackaging.
Restricted area:	Any area to which access is controlled for the protection of individuals from exposures to radiation and radioactive materials.
Secondary engineering control (SEC):	The area where the PEC is placed (eg, a classified area or an SRPA). It incorporates specific design and operational parameters required to minimize the risk of microbial contamination.
Segregated radiopharmaceutical processing area (SRPA):	A designated, unclassified space, area, or room with a defined (by facility procedures) perimeter that contains a PEC. An SRPA is only suitable for radiopharmaceutical preparation (with and without minor deviations), dispensing, and repackaging. If the SRPA is used to elute radionuclide generators it must have ISO Class 8 particle count non-viable particle count air quality.
Shielding:	Barriers of appropriate radiation attenuating material, used for radiopharmaceuticals, to protect the personnel. These barriers can be general in nature (eg, L-block, hot-cell), as to afford protection from a radiation field, or specific to a container used to hold a particular radiopharmaceutical (eg, syringe shield, vial shields, "pigs").
Single-dose container:	A container of a radiopharmaceutical for administration that is designed for use with a single patient as a single administration.
Specific activity:	The radioactivity of a radionuclide per unit mass of the compound involved with the radionuclide (see Radioactivity—Theory and Practice <821>). The units of specific activity involve those for the activity (eg, mCi, MBq, Ci, GBq)and those for the unit of mass (eg, µg, mmol)
Sporicidal agent:	A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Start of preparation:	Time at which a vial septum is punctured or a component container is opened (eg, removal of cap on a pre-filled syringe), whichever comes first.
Sterility:	The absence of viable microorganisms.
Strength:	The radioactivity concentration of the radiopharmaceutical at the calibration time (see <821>). Strength is expressed as the quantity of radioactivity on a volume basis (eg, mCi/mL or MBq/mL).
Unclassified space:	A space not required to meet any ISO air cleanliness classification.
Unrestricted area:	An area in which a person should not be exposed to radiation levels in excess of 2 millirems in any 1 h from external sources.
Use-by time:	For radiopharmaceuticals prepared from kits, the time period after preparation during which the radiopharmaceutical should be used or administered, as suggested or stated in the manufacturer's prescribing information.

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	945 N. Edgewood Ave., Suite A-1, Wood Dale IL 60191
NABP Business e-Profile ID:	1803196
VPP Inspection Date(s):	5/2/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N):	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	30 of 96	59.01	RLS (USA) Inc. SOP 6.2.2 Aseptic Technique and Preparation requires disinfection of gloves by spraying with sterile 70% IPA prior to reentinering a PEC after touching non-sterile surfaces such as pens and paper. All pharmacists and technicians have been retrained on this procedure and training documentation is on file.	6/15/2024	Y	SOP 6.2.2 Aseptic Technique and Preparation
Clarification or Further Explanation	88 of 96	339.00	RLS (USA) Inc. SOP 4.4.4 Self-Inspections and Program Reviews requires site self-inspections and program reviews of the QA/QC, Radiation Safety, and Environmental Health and Safety programs on a routine basis. Completion of the QA Program review was last documented for this facility on 6/12/2023. However, site personnel were unable to locate the program review at the time of the inspection. A review of the location of the documentation associated with the site self-inspections and program reviews has been conducted to ensure all applicable staff are aware of the document location during an inspection. Documentation of this training is on file.	6/15/2024	Y	SOP 4.4.4 Self-Inspections and Program Reviews
Clarification or Further Explanation	88 of 96	340.00	RLS (USA) Inc. SOP 4.4.4 Self-Inspections and Program Reviews requires site self-inspections and program reviews of the QA/QC, Radiation Safety, and Environmental Health and Safety programs on a routine basis. This SOP also requries non-conformances are investigated, and CAPAs (if any are identified) are implen..nted to prevent reoccurance. Documentation of these inspections and program reviews including corrective actions taken to any identified non-conformances are maintained in the Joint Commission Tracers with AMP® tool. Completion of the QA Program review was last documented on 6/12/2023 and is readily available to all personnel. A review of the location of the documentation associated with the site self-inspections and program reviews shall be conducted to ensure all applicable staff are aware of the document location during an inspection. Documentation of this training is on file.	6/15/2024	Y	Joint Commission Resources Tracer Observation Detail Report

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

2213

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	945 N. Edgewood Ave., Suite A-1, Wood Dale IL 60191
NABP Business e-Profile ID:	1803196
VPP Inspection Date(s):	5/2/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)

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Joint Commission Resources

Tracer Observation Detail Report

Quality Lead- Quarterly QA Program Review

05/23/2024 12:51 PM

Site: 535863 RLS (USA) Inc.

Program: Home Care

*Compliance percentage and totals display data from all questions in the observation.

100.0%

Total Numerator : 53 **Total Denominator : 53** **Not Applicable Count : 0** **Total Question Count : 53**

Observation Header

Tracer Instructions: Review site quality program compliance on a quarterly basis. Reviews are due by the last day of each month following the calendar quarter. Corrective actions to non-compliant findings which do not require an investigation shall be documented by assigning as associated task in this tool. Findings requiring investigations to determine cause and implement effective corrective actions shall be entered into the SAP system for proper documentation and tracking to closure.	
Observation Title: Quality Lead- Quarterly QA Program Review - Janice, Swett - 06/12/2023 10:23.740 AM	
Observation Status: Complete	**Regions:** West
Observation Date: 05/31/2023	**Department:** Wood Dale, IL
Total Completed Observations: 1	**Staff Interviewed:**
Survey Team:	**Unique Identifier:**
Medical Staff:	**Equipment Observed:**
Location:	**Contracted Service:**
Note:	

Questions (* = Required)

Cleaning/Maintenance and Infection Control

1.* Monthly quality self-inspection results been reviewed, corrective actions taken if required and corrective actions are appropriate and effective. ☐ N/A

Instructions: Review the monthly quality self-inspections for your facility to confirm compliance.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

2.* If the facility uses a third party vendor for cleaning the clean room, have all scheduled cleanings been completed per SOP, within the required time frame and documentation is clearly written and complete? ☐ N/A

Instructions: Review third party vendor clean room cleaning records for period under review, sign and date when review is completed. Confirm that the vendor has completed all scheduled cleanings on time (monthly cleaning every 30 days), appropriate cleaning agents are used per SOP and all records are complete, accurate, clearly written, signed as required and good documentation practices are followed.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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3.* Have all Clean Room equipment and environment filters been replaced or inspected as required by SOP and is proper documentation maintained? ☐ N/A

Instructions: Review Form 111 Filter Maintenance Record for timely completion of tasks required and proper documentation. LFH pre-filters are to be changed bi-annually unless otherwise required by local regulations, cart pass-thru filters are changed quarterly, air return filters (low wall air returns in clean rooms) are deep cleaned bi-annually.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.

4.* Has quarterly HVAC service been completed as required by SOP and is Form 112 Maintenance Checklist on file? ☐ N/A

Instructions: Review HVAC maintenance records on file. Confirm that service is completed during each quarter, annual maintenance service schedule is completed once per year and service provider is completing Form 112 for each service.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.
EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

5.* Have all laminar flow hoods LFH and biological safety cabinet BSC disinfection procedures been properly completed as required and documented accordingly? ☐ N/A

Instructions: Review Form 25 LFH and BSC disinfection logs for period under review. Confirm that all units were cleaned each day of use and frequency is appropriate as required by SOP and local regulations. Confirm an "A" agent for used daily, all entries are clearly written and good documentation practices are followed. Confirm that deep clean is performed at required frequency.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

6.* Aseptic processing areas are clean and uncluttered. All clean rooms have been cleaned each day of use as required by SOP and documented properly on Form 76. Monthly cleaning tasks performed timely and documented properly. ☐ N/A

Instructions: Review cleaning logs for period under review, sign and date when review is completed. Confirm that rooms were cleaned each day of use and monthly cleaning is performed. Confirm all documentation entries are complete and clearly written. Good documentation practices are followed.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.
MM.05.01.07 EP 2 - Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.

7.* Are ISO classified areas in good condition, no signs of wear, or deterioration? ☐ N/A

Instructions: Look through the clean room areas, looking for broken parts, breaks/tears/bubbling flooring, loss/deterioration of caulk, paint chips, buildup of cleaning agents, etc.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

8.* Has the restricted area been properly cleaned and maintained to aid in the control of the clean room environment? ☐ N/A

Instructions: Confirm maintenance is appropriate by observation of the restricted area for clutter and accumulation of dust/debris especially near the outer perimeter of the clean room. Documentation is not required.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

9.* Is storage of supplies in the clean room kept to a minimum, racks clean and neatly organized and opened syringes kept to 24 hour supply? ☐ N/A

Instructions: Visually observe the storage of supplies in the clean room. Confirm that supplies kept to a minimum and stored in containers that are easily cleanable when possible. No excessive supplies are stored in any area and the areas immediately surrounding the laminar flow hoods are clear of storage racks.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

10.* Hand hygiene practices follow the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5) ☐ N/A

Instructions: Verify that a legible copy of the WHO hand hygiene poster is posted at the hand hygiene sink.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

NPSG.07.01.01 EP 1 - Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) and/or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)

11.* Verify hand hygiene compliance tracking has been completed each January and July using Form 141 and were compliance goals met during these observations? (See also IC.03.01.01, EP 3) ☐ N/A

Instructions: Minimum acceptable overall or individual compliance goal is 80%. If less than 80% compliance was observed was the individual or entire staff re-trained and re-observed? Were the most recent observation compliance rates compared with the previous tracker? Was an improvement goal of +2% or more observed for overall facility compliance from the previous tracker until ultimate goal of 100% compliance is achieved and maintained?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

NPSG.07.01.01 EP 2 - Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
NPSG.07.01.01 EP 3 - Improve compliance with hand hygiene guidelines based on established goals.

12.* Are all deliveries being handled in a manner to reduce the possible spread of infections? (See also IC.02.02.01, EP 4) ☐ N/A

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Instructions: Confirm by observation and interview that distribution personnel understand and comply with segregation or covering of return packages from delivery packages, hand hygiene and equipment sanitization procedures.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.01.01.01 EP 9 - The organization delivers medical equipment and supplies that are sanitary, clean, and undamaged.

13.* Do site distribution personnel reduce possible cross contamination of delivery packages by using proper segregation and/or coverings on return delivery packages? ☐ N/A

Instructions: Confirm by observation and interviews that distribution personnel understand and comply with measures to reduce cross contamination during delivery procedures.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.01.01.01 EP 9 - The organization delivers medical equipment and supplies that are sanitary, clean, and undamaged.
IC.02.02.01 EP 1 - The organization implements infection prevention and control activities when doing the following: Cleaning and performing disinfection of medical supplies and devices. * Note: Disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/#r3. (See also EQ.01.05.01, EPs 3, 4)
IC.02.02.01 EP 3 - The organization implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies in accordance with law and regulation.
IC.02.02.01 EP 4 - The organization implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies. (See also EQ.01.05.01, EPs 1, 2, 3, 4, 5)

14.* Are proper supplies available for clean room entry hand hygiene? ☐ N/A

Instructions: Nail pics, hand soap in non-refillable dispensing containers, and low lint towels must be used for clean room entry hand hygiene.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Environmental Controls and Monitoring

15.* Have the clean room and primary engineering control certification reports been reviewed for compliance and timely completion? ☐ N/A

Instructions: Confirm that third party certification reports are reviewed and all primary and secondary engineering control tests have been completed according to SOP, USP<797> and State BOP requirements. Confirm that any failures or out of compliance results are investigated and remediation actions/corrective actions are taken.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 5 - The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.

16.* Is equipment used in compounding and to ensure proper storage conditions in calibration if required? ☐ N/A

Instructions: Review all drug storage thermometers/hygrometers, cold drug storage (refrigerator) thermometers, heat block thermometers, centrifuges, velometer and tachometer to verify that equipment is in calibration. Calibration reports shall be signed and dated to document the initial site review. Verify that calibration certificates are maintained on file for equipment currently in use and prior certificates are maintained on file for a minimum of 5 years.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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EQ.02.01.01 EP 4 - The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.

17.* Have viable air samples been taken at the appropriate frequency, at all locations as required in SOP and confirmed to be within ISO classification limits? If samples exceeded action limits, was remediation conducted and properly documented with corrective actions? Was area retested to confirm state of control? ☐ N/A

Instructions: Review certification records for period under review to confirm that viable air samples have been completed as required and are within ISO classification requirements. Confirm Action limits are not exceeded. Confirm that any exceedences are reported, investigated and corrective actions if identified are implemented and communicated to applicable employees. Confirm that follow up activities to determine effectiveness of corrective actions taken are documented. If applicable, confirm that any reporting of excursions to State Board of Pharmacy was completed.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

18.* Has contact plate surface sampling been conducted at the required frequency and confirmed to be within ISO classification action limits? If exceedences are identified, was organism(s) ID'd, remediation conducted and properly documented? ☐ N/A

Instructions: Review records during period under review to confirm that contact plate tests for surface contamination have been completed as required and are within ISO classification requirements. Confirm that SOP action limits are not exceeded. Confirm that any exceedences are ID'd by a credentialed lab, reported, investigated and corrective actions if identified are documented and communicated to applicable employees. Confirm that follow ups activities to determine effectiveness of corrective actions taken are conducted and documented. If applicable, confirm that any required reporting of excursions to State Board of Pharmacy was conducted.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

19.* Are temperature and humidity readings taken each day of operations in all drug and media storage locations and verified to be within required ranges? ☐ N/A

Instructions: Review temperature and humidity logs Form 28 for period under review. Confirm proper documentation each day of operations or as required by State regulations. Documentation is clearly written, and all temperatures and humidity readings are within appropriate ranges per SOP and State BOP guidance. If out of specification results are noted, were corrective actions needed to return the area to the proper range? Were corrective actions noted or documented?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.03.01.01 EP 2 - For organizations that store medications at their site(s): The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. Note: This element of performance is also applicable to sample medications.
MM.03.01.01 EP 4 - For organizations that store medications at their site(s): The organization follows a written process addressing the control of the medication between receipt by the organization and delivery to or administration at the designated site. Note: This element of performance is also applicable to sample medications.

20.* Are pressure differentials recorded each day of operations and verified to be within required ranges? ☐ N/A

Instructions: Review Form 82 pressure differential logs for period under review. Confirm that pressure differentials are documented at minimum once each day of operations, documentation is clearly written, and all pressure differentials are within appropriate ranges per SOP guidance. If out of specification results are identified, were corrective actions taken to remediate and properly documented?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

21.* Verify environmental monitoring results have been trended on the EM trending spreadsheet and evaluated for negative trends. Negative trends if any, have been identified and actions taken as needed. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

22.* Are all drugs, components, drug kits, and environmental monitoring media stored correctly and are storage areas monitored using calibrated thermometers/hygrometers? ☐ N/A

Instructions: Perform a review of the room drug storage area and drug product storage areas to ensure label storage conditions are met. If any of these products require refrigerator, freezer, or low humidity storage, these areas must be monitored using a calibrated monitoring device (thermometers and/or hygrometers). Ensure products are not stored outside of monitored areas.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Employee Competencies and Process Validations

23.* Have employees and third party vendors who perform duties in the clean room been visually observed for the duties they perform: initially and at frequencies as required by aseptic training policy? ☐ N/A

Instructions: Review observational assessment Forms 114-118 on file. Confirm that initial and subsequent observational assessments have been completed on each site employee and third party vendors for all duties performed in the clean room in a timely manner. Confirm that no observational assessments are past due.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

24.* Have all employees who perform compounding and drawing activities performed the applicable media fill validations initially prior to performing duties and been re-evaluated at the appropriate intervals in accordance with SOP? ☐ N/A

Instructions: Review media fill records for the period under review for compliance to SOP. If a media fill failure is noted, have investigation procedures and re-evaluation as outlined been completed, documented and reported?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

25.* Have all employees who perform WBC labels performed a WBC media fill validation initially prior to performing duties and been re-evaluated at the appropriate intervals in accordance with SOP? ☐ N/A

Instructions: Review WBC media fill records for the period under review for compliance to SOP. If a media fill failure is noted, have investigation procedures and re-evaluation been completed, documented and reported?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

26.* Have all employees who perform aseptic compounding or dose drawing performed gloved fingertip sampling as required by SOP? Initial GFT sampling must be completed on 3 separate and full garbing procedures. Re-evaluation GFTs are conducted as part of the media-fill process. ☐ N/A

Instructions: Review gloved fingertip sampling records. Confirm that all applicable employees have completed initial triplicate fingertip sampling to verify proper garbing technique and fingertip samples during media fills to confirm aseptic technique prior to performing aseptic operations. Confirm that employees are sampled at appropriate frequency in compliance with SOP during a media fill operation. If action limits are exceeded, are investigations into the possible cause conducted, employees re-instructed, re-evaluated and properly documented in the reporting tool?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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27.* Has product sterility testing been completed annually as required by SOP or more frequently if required by local BOP rules? ☐ N/A

Instructions: Review Form 119 to confirm that sterility testing has been completed as required by SOP at minimum annually or as required by local BOP rules. If a positive sterility test was observed, was failure properly reported, investigated, corrective action if identified are implemented and communicated to applicable employees? Confirm that follow up activities to determine effectiveness of corrective actions taken are documented in the reporting tool.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

28.* Are all the staff's required licenses, certifications, or registrations, posted in the facility and not expired? Is Form 42 completed, and up-to-date? *If any licenses are due to expire within the upcoming calendar quarter, assign a TASK for that employee using this tracer, requiring them to provide proof of renewal prior to the expiration date. ☐ N/A

Instructions: Staff licenses, certifications, registrations required by the company, BOP or a State agency must be verified through the issuing agency website upon hire, and prior to each expiration. If you use floaters, their license must be checked prior to performing duties at your site, if the license has not been verified by their primary worksite site since the last renewal date. If your state requires the company maintains record of CE required for license/certification renewal, documentation must be presented to the PIC at the time of renewal and maintained on file.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

HR.01.01.01 EP 2 - The organization verifies and documents the following: - Credentials of staff using the primary source when licensure, certification, or registration is required by law and regulation to practice their profession. This is done at the time of hire and at the time credentials are renewed. - Credentials of staff (primary source not required) when licensure, certification, or registration is not required by law and regulation. This is done at the time of hire and at the time credentials are renewed. For home health agencies that elect to use The Joint Commission deemed status option: The organization maintains current licensure and qualifications in personnel records. Note 1: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented. Note 2: A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source. Note 3: An external organization (for example, a credentials verification organization [CVO]) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

29.* Have the appropriate aseptic assessments been completed on any new hire or employees whos duties have changed to require entry ISO classified areas prior to entry? ☐ N/A

Instructions: All employees who enter an ISO classified area must be trained and then assessed on their aseptic techniques applicable to their assigned duties.
Entry requires: 1) Hand hygiene and garbing training and observational assessment
2) Initial Gloved fingertip tests on three separate hand hygiene and garbing entries
Cleaning/disinfecting requires: 1) Cleaning/disinfecting observational assessment for each area they are assigned duties
Product prep/dose drawing requires: 1) Aseptic technique assessment
2) Media fill/GFT testing for assigned duties

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Training

30.* Have all employees completed the initial and annual USP training module in a timely manner? ☐ N/A

Instructions: Review training records to confirm that all new employees have completed the initial USP training module(s) appropriate to their job description and prior to performing clean room related tasks. Annual reviews are completed by all employees within the past year. No training is past due.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

31.* Are employee who perform WBC labeling and WBC Dual Verifications up to date on training required in SOP? ☐ N/A

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Instructions: Confirm by reviewing electronic and/or hard copy training records to confirm all employees who perform WBC labeling procedures and Dual Verifications are trained initially and annually thereafter as required by SOP.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

32.* Do all employees who perform Therapy Order Verifications have a Form 49 on file? ☐ N/A

Instructions: Confirm that all employees who perform therapy order verifications are initially trained (Form 49 on file).

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

33.* Are Management of Change MOC activities properly implemented and communicated to site employees? ☐ N/A

Instructions: Review site electronic and/or hard copy MOC documents including training records for the quarter under review. Confirm that employees have acknowledged training on Change packets or signed hard copy training records if changes were applicable to their job duties. Verify that MOC changes have been properly implemented and new forms and procedures are being utilized.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

34.* The PIC has reviewed SOPs associated with the overall QA/QC site program within the last 12 months against current employee practices and State BOP requirements. ☐ N/A

Instructions: This review is documented on Form 120. Corrective actions are taken to ensure SOPs reflect current practices and Fed/State regulatory requirements.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

35. Confirm by review of change packet documentation that any program changes implemented during the quarter have been fully implemented and all applicable personnel have been trained on these program changes. ☐ N/A

Instructions: MOC training records are maintained on file either hard copy or electronically for all affected employees.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

Compounding and Preparation

36.* Does the facility assign appropriate expiration dating to compounded drugs and drugs used in compounding procedures in compliance with policies and procedures? ☐ N/A

Instructions: Check pharmacy computer system for maximum activity and expiration times on all compounded drug products. Verify that the site has on file complete stability data by drug manufacturer for all drugs compounded beyond package insert activity and expiration time. Confirm that kit calibration times match actual compounding times within 15 minutes. Confirm that no new drugs or manufacturers were introduced during the period under review and if so, maximum activity and expiration times assigned are set to package insert or are supported by complete stability records on file. Confirm by observation and interviews that single use bag/vials of diluents used during compounding are labeled with open date/time if used during multiple runs or discarded at end of run. No single use vial or bag punctured inside an ISO 5 environment is used for more than 6 hours.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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37. Are medications and components stored in accordance with manufacturer's recommendations or, in the absence of such recommendations, in accordance with PIC's instructions? Are high alert medications, look-a-like/sound-a-like medications properly labeled, stored and handled as indicated in SOP 3.2.4? ☐ N/A

Instructions: Confirm compliance by inspecting drug storage areas. Observe procedures and review associated documentation for compliance (Y-90, Bexxar, therapy medication, WBC labeling, etc.). Confirm proper order processing and handling of look-a-like/sound-a-like drugs as described in SOP.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.01.01.03 EP 1 - The organization identifies, in writing, its high-alert and hazardous medications. * Note: This element of performance is also applicable to sample medications. Footnote *: For a list of high-alert medications, see https://www.ismp.org/recommendations. For a list of hazardous drugs, see https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf. (See also EC.02.02.01, EP 1)
MM.01.01.03 EP 2 - The organization follows a process for managing high-alert and hazardous medications. Note: This element of performance is also applicable to sample medications. (See also EC.02.02.01, EP 2)
MM.01.02.01 EP 1 - The organization develops a list of look-alike/sound-alike medications it stores, dispenses, or administers. Note 1: One source of look-alike/sound-alike medication name pairs is the Institute for Safe Medication Practices (https://www.ismp.org/recommendations/confused-drug-names-list). Note 2: This element of performance is also applicable to sample medications.
MM.01.02.01 EP 2 - The organization takes action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.
MM.01.02.01 EP 3 - The organization annually reviews and, as necessary, revises its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.
MM.03.01.01 EP 2 - For organizations that store medications at their site(s): The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. Note: This element of performance is also applicable to sample medications.

38.* Are large volume parenterals divided in compliance with SOP, properly stored and labeled? ☐ N/A

Instructions: Confirm by observation that large volume parenterals are divided and labeled in compliance with SOP and given proper expiration dating.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

39.* Are drugs which have expired, are damaged, contaminated or have been recalled properly handled and quarantined in a designated area away from active product prior to final disposal in compliance with SOP? ☐ N/A

Instructions: Confirm by review of computer inventory that expired and recalled drugs are not in active inventory. Inspect quarantined product storage area for proper segregation.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.03.01.01 EP 8 - All expired, damaged, and/or contaminated medications are removed from patient care areas and stored separately from medications available for administration. Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 1 - The organization follows a written policy describing how it will retrieve and handle medications within the organization that are recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA). Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 3 - For organizations that store or dispense medications: When a medication is recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA), the organization notifies the prescribers and those who dispense or administer the medication. Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 4 - When required by law and regulation or organization policy, the organization informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA). Note: This element of performance is also applicable to sample medications.

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40. Confirm by review of local documents and observation that product information is properly confirmed at time of receipt and labeled with Auxiliary Control # labels and Auxiliary Barcode labels as required in SOP 3.2.2. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.02.01.01 EP 4 - The organization maintains a written list of medications, including strength and dosage, for dispensing and administering. The list of medications is readily available. Note: In some settings, the term "formulary" is used instead of "list of medications available for use." The terms are synonymous. (See also MM.03.01.01, EP 1)
MM.03.01.01 EP 1 - For organizations that store medications at their site(s): The organization stores only approved medications and medications selected by the organization. (See also MM.02.01.01, EP 4)
MM.03.01.01 EP 4 - For organizations that store medications at their site(s): The organization follows a written process addressing the control of the medication between receipt by the organization and delivery to or administration at the designated site. Note: This element of performance is also applicable to sample medications.

41.* Confirm by review of local documents and that a master formula is on file in hard copy or electronic copy for each product prepared with minor deviations or compounded as described in Policy 6.5. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

42.* Confirm by review of pharmacy computer system that all maximum activities and expiration times which exceed the manufacturers recommendations are supported by stability data required in SOP 6.5.2. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

43. Confirm by review of current inventory and inventory records that only appropriate, conventionally manufactured sterile products from FDA-registered facility are used in product preparation. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.02.01.01 EP 2 - The organization develops and approves criteria for selecting medications, which include the following: - Indications for use - Effectiveness - Drug interactions - Potential for errors and abuse - Adverse drug events - Sentinel event advisories - Other risks - Costs Note: This element of performance is also applicable to sample medications.
MM.02.01.01 EP 4 - The organization maintains a written list of medications, including strength and dosage, for dispensing and administering. The list of medications is readily available. Note: In some settings, the term "formulary" is used instead of "list of medications available for use." The terms are synonymous. (See also MM.03.01.01, EP 1)

44. All vial shields are properly labeled whenever radiopharmaceuticals are prepared. (See also MC.03.08.05, EP 1; MC.05.01.01, EPs 4 and 6; MM.06.01.01, EP 3) ☐ N/A

Instructions: Vial shield labels are undamaged, cleanable. Auxiliary control # labels are placed on shields prior to preparation.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.05.01.09 EP 1 - Medication containers are labeled whenever medications are prepared but not immediately administered. Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process. Note 3: This element of performance is also applicable to sample medications.

Quality Events/Performance Improvement

45.* Are all quality related events reported to the facility through customer or patient complaints such as the right dose, right drug, right patient/customer, right time, on time, and product safety events such as altered biodistribution, adverse events, patient complaints etc., being properly reported in the electronic database and being investigated for appropriate corrective actions? Are external reports being made as required by law or regulation? ☐ N/A

Instructions: Confirm by reviewing reported events for complete and clearly written documentation, references to all investigation activities, identification of corrective actions and follow up documentation showing effectiveness of corrective actions. Confirm external reports are timely if needed. Confirm that site personnel can retrieve supporting documents that are not supplied as attachments to the event.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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LD.03.07.01 EP 2 - As part of performance improvement, leaders, or managers delegated by leaders, do the following: - Set priorities for data collection, performance improvement activities, and patient health outcomes - Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities Note: Examples of areas of risk include blood-borne infections, wound care, undetected urinary tract infections, oxygen-related fires, and patient handoff to or from the home care organization. - Identify the frequency of data collection for performance improvement activities - Reprioritize performance improvement activities in response to changes in the internal or external environment Note: For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care. (See also PI.01.01.01, EPs 2, 12, 13; PI.02.01.01, EP 1)
PI.01.01.01 EP 12 - The organization collects data on the following: Significant medication errors. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 13 - The organization collects data on the following: Significant adverse drug reactions. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 15 - The organization collects data on the following: - Patient satisfaction with and complaints about products and services - Timeliness of response to patient questions, problems, and concerns - Impact of the organization's business practices on the adequacy of patient access to equipment, items, services, and information - Adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infection, and hospitalizations)
PI.01.01.01 EP 2 - The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.03.07.01, EP 2)
PI.01.01.01 EP 41 - For specialty pharmacies: The organization collects data on medication errors including the following: - Incorrect drug - Incorrect recipient - Incorrect strength of medication - Incorrect dosage form - Incorrect instructions - Incorrect quantity - Near misses
PI.01.01.01 EP 42 - For specialty pharmacies: The organization collects data on the following: - Adherence rate - Turnaround time for patient delivery of medications and associated products supplied by the specialty pharmacy Note: The organization may choose to separate data for medications that require an intervention. - Billing and coding errors

46.* Are quality events and corrective actions being properly communicated to all affected employees and employee training completed? ☐ N/A

Instructions: Confirm that events are being properly communicated to affected employees by reviewing site communications documents such as monthly safety meeting minutes or completion of training record on Form 45.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

LD.03.07.01 EP 2 - As part of performance improvement, leaders, or managers delegated by leaders, do the following: - Set priorities for data collection, performance improvement activities, and patient health outcomes - Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities Note: Examples of areas of risk include blood-borne infections, wound care, undetected urinary tract infections, oxygen-related fires, and patient handoff to or from the home care organization. - Identify the frequency of data collection for performance improvement activities - Reprioritize performance improvement activities in response to changes in the internal or external environment Note: For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care. (See also PI.01.01.01, EPs 2, 12, 13; PI.02.01.01, EP 1)
PI.01.01.01 EP 12 - The organization collects data on the following: Significant medication errors. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 13 - The organization collects data on the following: Significant adverse drug reactions. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 15 - The organization collects data on the following: - Patient satisfaction with and complaints about products and services - Timeliness of response to patient questions, problems, and concerns - Impact of the organization's business practices on the adequacy of patient access to equipment, items, services, and information - Adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infection, and hospitalizations)
PI.01.01.01 EP 2 - The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.03.07.01, EP 2)

47.* Are corrective actions to quality events implemented and are follow ups conducted to confirm effectiveness? ☐ N/A

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Instructions: Confirm by reviewing events for identified corrective actions. Do documents and/or interviews with employees confirm that corrective actions have been implemented? Have re-occurrences of the event or similar events happened which may show lack of effectiveness?

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)
PI.04.01.01 EP 4 - The organization evaluates actions to confirm that they resulted in improvements. Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that improvement actions are evaluated for effectiveness.
PI.04.01.01 EP 5 - The organization acts when it does not achieve or sustain planned improvements.

48.* Do site events show any re-occurrences or trends that have not been previously identified and that needs to be investigated for possible site or systemic corrective actions? Answer compliant if no re-occurrences or trends. ☐ N/A

Instructions: Confirm by review of site events for the period under review. Pay close attention to similar types events and look for trends that may show a breakdown of the quality system in place. If a trend is identified, an investigation into possible causes and corrective actions is to be initiated locally. If a systemic issue and corrective actions is identified a Management of Change shall be initiated.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.03.01.01 EP 4 - The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
PI.04.01.01 EP 5 - The organization acts when it does not achieve or sustain planned improvements.

49.* Have all product related complaints reported to or noted by pharmacy staff such as altered bio-distributions, adverse reactions and QC failures been reported to the drug manufacturer as required by SOP? ☐ N/A

Instructions: Review events entries for the period under review. Confirm that any product related complaints have been reported directly to the drug manufacturer.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.07.01.03 EP 1 - The organization follows a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.
MM.07.01.03 EP 2 - The organization follows a written process addressing prescriber notification in the event of an adverse drug event, significant adverse drug reaction, or medication error. Note: This element of performance is also applicable to sample medications.
MM.07.01.03 EP 3 - The organization complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.

50.* Has the site posted updated local communicable disease information for employees to review? ☐ N/A

Instructions: Confirm by observation that the local communicable disease postings are updated quarterly. The posting shall include influenza rates during the flu season. If an updated posting is not available, the current posting should be signed and dated as updated.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

IC.01.03.01 EP 1 - The organization identifies infection risks based on the following: - Its geographic location, community, and population served - The care, treatment, or services it provides - The analysis of its surveillance activities and other infection control data Note 1: Surveillance activities may address processes and/or outcomes. Note 2: For organizations that provide personal care and support services: Surveillance activities may include verification of infection control education for all employees and supervisor observations of employees' hand-washing techniques.
IC.01.03.01 EP 3 - The organization prioritizes the identified risks for acquiring and spreading infections. These prioritized risks are documented.

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51.* Has the facility completed the hand hygiene compliance tracker as required and does the facility meet company goals for hand hygiene compliance? ☐ N/A

Instructions: Confirm by reviewing local documents. If hand hygiene compliance did not meet goals, were corrective actions taken to promote compliance and were follow up observations made to confirm effectiveness of corrective actions? Current frequency is biannual (January/July of each year).

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

NPSG.07.01.01 EP 1 - Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) and/or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)
NPSG.07.01.01 EP 2 - Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
NPSG.07.01.01 EP 3 - Improve compliance with hand hygiene guidelines based on established goals.

52.* Confirm the current year Organizational Goals are posted and all employees are aware/understand these goals. Do employees know how we improve our performance to our goals through Continuous Quality Improvement (CQI)? ☐ N/A

Instructions: When interviewed, can staff name a goal or a quality improvement change that was implemented within the last year, i.e., an SOP change, or local change made in response to site event trending or customer complaint?

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

LD.02.01.01 EP 1 - Leaders work together to create the organization's mission, vision, and goals, which guide the leaders' actions and are communicated to staff and the population(s) the organization serves.
PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

53.* Are employees following Policy 4.3 and SOP 4.3.2 to respond to actual or potential adverse drug events, significant adverse drug reactions and medication errors? Staff Pharmacists follow procedures to notify affected prescribers. (See also MC.02.01.13, EP 2) ☐ N/A

Instructions: Verify by reviewing events and/or employee interviews.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

MM.07.01.03 EP 1 - The organization follows a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.

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SOP 4.4.4 Quality and Safety Self-Inspections and Program Reviews

I. Purpose

To describe quality and safety compliance self-inspections and program reviews.

II. Scope

This applies to all Nuclear Pharmacy sites.

III. Responsibility

It is the responsibility of the Pharmacy Manager or designee to oversee policy compliance for personnel under his/her supervision.

IV. Definitions

PIC- Pharmacist in Charge

V. Related Forms

Form 120 Quality Policy and Procedures Review Log

VI. Equipment and Materials:

All equipment and materials used in aseptic processing

VII. Procedure

A. Site Self-Inspections

1. Periodic self-inspections shall be conducted by each facility to ensure ongoing program and regulatory compliance.
2. Tracers with AMP® shall be used to record and maintain documentation of self-inspections either electronically or by printing a hard copy.
3. Content and minimum frequency of the self-inspections shall be determined by the QA/RA, EHS departments.
4. Tracer names and minimum required frequencies are listed in Table 1.
5. Issues identified during the self-inspections shall be documented to include the following:
    a. Description of issue identified
    b. Investigation details including root cause(s) if identified
    c. Corrective action and preventative actions (CAPAs) taken to prevent reoccurrence
    d. CAPA effectiveness evaluation if deemed necessary

B. Site Ops Metrics and Quality Program Reviews

1. Each site PIC/Manager or designee will report all Ops Metrics data by using the Ops Metrics reporting tool link on the E-Reporting and Requesting document found on Teams: https://forms.monday.com/forms/62687754c09f36ac1fa30af545d54340?r=use1

a. Ops Metrics data should be reported by the 15th of each month for the previous month.

2. Quality policies and procedures shall be reviewed annually by the PIC and documented on Form 120 for site compliance and applicability.
    a. This review will include but is not limited to the following:
    - Policy 2.2 Dose Calibrator and all associated SOPs

- Policy 2.3 Radiation Detection Equipment and all associated SOPs
- Section 3: Medication Management
- Policy 4.3 Patient Safety Events & Product Complaints and associated SOPs
- Policy 4.4 Pharmacy Regulatory Events and Inspections and associated SOPs
- Section 6: Quality Assurance- Medication Compounding
- Section 7: Blood Procedures and Controls
- Section 9: Pharmacy Wholesale Distribution

b. Any discrepancies between written procedures and state regulations shall be identified by submitting a management of change request.

3. The site PIC or designee shall review all new or revised policies and procedures and develop a local implementation plan. Hard copy Form 45 or electronic training records of implementation shall be maintained.

Table 1:

Tracer Name	Minimum Frequency	Suggested Responsibility
Monthly Vehicle Safety Check	Monthly on each company vehicle	Courier/Driver
Monthly EHS Safety Self-Inspection	Monthly	Any trained staff member
Monthly Quality Self-Inspection	Monthly	Any trained staff member
RSO- Monthly Rad Safety Inspection	Monthly	RSO
Quality Lead- Quarterly QA Program Review	Each calendar quarter	Quality Lead or Manager/PIC
EHS Lead- Quarterly Program Review	Each calendar quarter	EHS Lead or Manager/PIC
Quarterly Radioactive Medical Waste (RMW) Self-Inspections- State specific checklists for California, Florida, and New York	Each calendar quarter for sites in specified States	RSO
Biannual Hazardous Material (HMT) Self-Inspection	Biannual	EHS Lead or Manager/PIC
Biannual Form 141 Hand Hygiene Tracer Results	Every January and July	Quality Lead or Manager/PIC
Biannual Emergency Drill Confirmation	Biannual	EHS Lead or Manager/PIC
Medication Management Compliance	Annually	Manager/PIC
Annual OSHA Work Related I&I Reporting/Posting	Each year by February 1st thru April 30th	Manager/PIC
Contract Courier Observational Assessment	Optional or as needed for finding corrective actions	Any trained staff member
Packing and Shipping RAM Observational Assessment	Optional or as needed for finding corrective actions	Any trained staff member

VIII. Training

Employees performing these duties shall be trained on the procedure and the documentation tools.

LIST OF ATTACHMENTS

None

Document History		
Version	Date	Brief Description of Change
1	1 June 2020	New Document
2	1 Dec 2020	Updating SOP to remove quality audit which are now covered in SOP 4.4.3, identify required periodic self-inspections, and include form 140 on self-inspections and moved SOP # from 6.1.1 to 4.4.4.
2.1	1 Nov 2021	Administrative
2.2	1 Jul 2022	Updated for self-inspections to be recorded in Tracers with AMP tool, remove reference to Form 140.
2.3	1 Nov 2022	JC Finding- Update to identify required self-inspections by name, location, and frequency. Update to include location and required completion of Ops Metrics.

SOP 6.2.2 Aseptic Techniques & Preparation

I. Purpose:
To describe the aseptic technique used while compounding and dispensing sterile radiopharmaceuticals and pharmaceuticals.

II. Scope:
This applies to all Nuclear Pharmacy sites. Aseptic technique procedures will be employed when preparing for, and during all sterile product processing.

III. Responsibility:
It is the responsibility of the Business Unit Manager or designee to oversee policy compliance for personnel under his/her supervision. All pharmacists and supervised pharmacy support staff who prepare sterile products will adhere to these procedures.

IV. Definitions:

A. **Air curtain** – is the air boundary at the face of a LFH and BSC
B. **ALARA** – As Low as Reasonably Achievable
C. **Beyond Use Date (BUD)**- The date or time after which a compounded product or component used in compounding shall not be used.
D. **Buffer Area** – The area where the primary engineering control that generates and maintains an ISO Class 5 environment is physically located.
E. **CR** – Clean Room, which refers to all ISO classified areas
F. **Critical Sites** – Locations that include any component or fluid pathway such as vial septa, injection ports, open ampules, syringe tips, needles and needle hubs that are exposed and at risk of direct contact with air or touch contamination
G. **Critical Work Area** – Central area within the laminar air flow hood
H. **CSP** – Compounded Sterile Preparation
I. **Direct Compounding Area (DCA)** – A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA filtered air (first air)
J. **First Air** – The unidirectional air exiting the HEPA filter that is essentially particle free
K. **Multiple-Dose Containers**- A multiple-dose container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.
L. **Primary Engineering Control (PEC)** –Laminar flow hood (LFH) and Biological Safety Cabinet (BSC) which provide an ISO Class 5 environment for the exposure of critical sites
M. **Secondary Engineering Control (SEC)** – Clean Room ISO Class 8 ante and ISO Class 7 buffer areas which serve as a core for the location of the PEC
N. **Single-Dose Containers** - Single-dose containers are single-unit containers for articles or preparations intended for parenteral administration only.
O. **Restricted Area** – Radiation Restricted Area as defined for each individual facility

V. Related Documents:
None

VI. Equipment and Materials:
None

VII. Procedure:
A. All employees entering the clean room shall:

1. Maintain good personal hygiene
2. Perform thorough hand cleaning
3. Select and properly don appropriate garb
4. Clean and maintain the environment in accordance with the ISO classification of each area
5. Protect personnel and compounding environments from contamination
6. Offer guidance when observing incorrect procedures and report malfunctioning equipment.

B. All employees performing aseptic operations shall:
   1. Accurately and aseptically compound and dispense sterile products
   2. Properly label all CSP
   3. Inspect all CSP prior to release

C. To aid in maintenance of ISO classified air quality and first air:
   1. Only personnel directly involved in compounding or dispensing should be in the buffer rooms while aseptic processes are in progress.
   2. Dynamic occupancy rates tested during the current certification test should not be exceeded during aseptic operations.
   3. Verify LFH has proper air velocity prior to use by visual inspection of the airflow monitor or magnahelic gauge.
      a. If the LFH airflow monitor indicates the velocity is below the manufacturer's acceptable level for operation, the pre-filters shall be replaced. If the air velocity remains below the acceptable level after changing the pre-filters, the unit shall not be used.
   3. Verify BSC has proper air velocity prior to use each day by visual inspection of the magnahelic gauge and record the reading on Form 25.
      a. A significant change in the magnahelic gauge reading the time of calibration will indicate cause for concern and the unit shall not be used until service personnel can evaluate proper function.
   4. All personnel while working in the CR shall avoid excessive and fast movement that may compromise the air quality inside the ISO Class 5 PEC. This includes:
      a. Flapping of hands to dry gloves
      b. Quick movements near a PEC or through the air curtain at the face of the PEC
      c. Placement, pulling or swinging of the dose calibrator well dipper pulley in such a way that the pulley moves in and out of the ISO Class 5 air during aseptic operations
   5. Only essential personnel and items shall be in the immediate area of an ISO Class 5 PEC during aseptic processing. The immediate area shall be a minimum of 3 feet in front of any ISO Class 5 PEC.
   6. Talking shall be kept to a minimum and directed away from the PEC during aseptic processing.
   7. Operators shall not interfere with the first air flowing directly from the PEC HEPA filter to critical sites during manipulations.
      a. Radiation safety practices must be balanced with aseptic handling practices when handling radioactive materials. The use of flanged syringe shields and recessed vial shielding may disrupt direct first air contact with the vial septum during certain handling conditions.
      b. The operators' hands or any equipment shall not be allowed to block or interrupt HEPA filtered air to critical sites e.g., unsheathed needle, open centrifuge tube, exposed barrel tip and punctured vial septum when radiation safety practices are not a factor, e.g., drawing saline into a syringe.
   8. Only supplies critical to aseptic operations may be introduced into the PEC.
      a. Items placed in the PEC shall be disinfected using a sterile wiper and sterile 70% IPA.
      b. Unit dose pigs shall be cleaned and disinfected within 24 hours prior to the production run.
      c. Equipment and absorbent material shall not obstruct airflow return grates at the front and back of the work surface.

9. Saline bags and other products or devices shall be hung in the PEC to avoid obstructing first air to the DCA and to ensure critical sites are accessed at least 6 inches from the front edge and either side wall of the PEC.
10. A minimal number of absorbent pads may be used in the PEC for ALARA purposes and shall not block airflow grates at the front or back of the PEC.
11. Only supplies immediately necessary to kit compounding and dose dispensing activities shall be in the DCA.
12. Under normal operations, PECs should never be turned off. In the event of a power failure or shut down for maintenance or service, the unit must be:
    a. Turned on and allowed to run for a minimum of 30 minutes to allow purging of contaminated air and full circulation of first air.
    b. Cleaned with a List A agent and disinfected with sterile 70% IPA prior to use.

D. General Principles of Aseptic Technique
1. Aseptic principles are used during preparation of CSPs to ensure they are free of microorganisms, pyrogens, and particulate matter. It involves the manipulation of products, vials, syringes and the shielding necessary to reduce radiation exposure with consideration to airflow to produce a sterile final product.
2. All aseptic manipulations shall be conducted in a properly prepared ISO Class 5 PEC while wearing appropriate garb.
3. Compounding, dose dispensing, removing, changing, or adding a needle, and vial or bag punctures or any action that involves exposing a critical site to potential contamination shall be considered an aseptic manipulation.
4. Vial septa and bag injection ports shall be disinfected before puncturing, after being exposed to less than ISO 5 air, and if touch contamination is known or suspected. Disinfection shall be performed:
    a. inside the PEC prior to initial puncture
    b. using a new sterile 70% IPA swab
    c. by wiping three times in the direction of the operator
    d. prior to another needle puncture if vial shield top is closed or product is removed from the ISO 5 environment
    e. frequently whenever multiple punctures are occurring
5. Critical sites such as the needle shaft and tip, the syringe plunger ribs, and barrel tip cannot be disinfected and must be discarded if touch contamination is known or suspected.
6. Care must be taken to avoid touching the plunger ribs when drawing sterile products into syringes. If plunger ribs have been or are suspected to have touch contamination:
    a. You may continue with the action of pulling product into the syringe.
    b. You may eject one time as needed e.g., during kit preparation.
    c. You may NOT move the plunger back and forth to adjust activity/volume because the product may become contaminated.
7. Needles shall be used immediately upon removing the cap and promptly recapped or discarded after use.
8. Syringes containing diluents or sterile products for future use may not have the needles removed unless replaced with a sterile cap.
9. Syringes and needles must be discarded if needles are uncapped or removed from syringes in an environment other than ISO Class 5 air quality.
10. Operators shall disinfect their gloves by spraying all surfaces with Sterile 70% IPA:
    a. Immediately after donning sterile gloves.
    b. Prior to cleaning the PEC.

c. Immediately prior to each kit preparation after all disinfected components for compounding have been properly introduced into the PEC.
d. Immediately prior to each dose drawing activity after proper line clearance has been completed and the kit has been properly introduced into the PEC.
e. Immediately prior to initiating each WBC processing action conducted inside the BSC.
f. Prior to re-entering the PEC after touching non-sterile surfaces such as phones, barcode scanners, pens, paper, carts, generators, heat block containment box, tables, etc.
g. Periodically throughout prolonged sessions of compounding or dose drawing or when suspected or known contaminant has occurred.

D. Assignment of BUDs
1. Sterile and Non-sterile prepared products:
a. Shall not exceed the manufacturer's expiration date or time of the component(s) used in compounding.
b. Non-sterile shall be compliant with current USP<795> guidelines.
c. Sterile radiopharmaceutical shall be compliant with current USP<825> guidelines.
d. Sterile radiopharmaceuticals prepared from cold kits shall be compliant with SOP 6.5.2/CASOP 6.5.2 Stability Testing when applicable.
2. Single dose containers:
a. Must be punctured within an ISO Class 5 environment with proper aseptic technique.
b. Must be properly labeled with the BUD date and time.
(a) Single-dose containers used during a single production run not exceeding 6 hours and remaining under the control of a single operator, need not be labeled but must be discarded at the end of the single production run.
c. Maximum BUD is 6 hours and must be discarded 6 hours after the initial needle puncture.
3. Multiple dose containers:
a. Must be punctured within an ISO Class 5 environment with proper aseptic technique.
b. Must be properly labeled with initial puncture date and discard date.
c. Maximum BUD is 28 days after initial needle puncture unless otherwise specified by the manufacturer.
d. BUD shall not exceed the manufacturer's expiration date.

VIII. Training

All employees who perform aseptic operations shall be trained on this procedure.

LIST OF ATTACHMENTS

None

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1	1 June 2020	New Document
1.1	15 Sept 2021	Changed incorrect reference to sterility testing policy.
1.2	1 Nov 2021	Administrative
1.3	1 Nov 2022	Update C.4. in response to JC finding regarding dose calibrator dipper swinging in and out of ISO Class 5 air space during product preparation and dose drawing.

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FS3957466
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Saveway Compounding Pharmacy, LLC

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 3023695520 Toll Free # (NAC 639.708, NRS 639.23286): 8772858143

Fax: 3023695853 Contact Email: license@savewaypharmacy.com

Website: www.savewaypharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Pradeep Chilakapati

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22784

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Pradeep Chilakapati	NV Pharmacist Registration #: 22784
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Myonex, LLC

Corporation/Organization Name: Saveway Compounding Pharmacy, LLC

Mailing Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Telephone: 3023695520 Email: license@savewaypharmacy.com

Contact Person Name: Pradeep Chilakapati, PIC

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for Saveway Compounding Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Gregory T Lavin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

19 July 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregory T Lavin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

19 July 2024

Date

Board Use Only	Date Received: 7/22/24	Amount: $500 - CC

SAVEWAY
COMPOUNDING
PHARMACY, LLC

Explanation to Section 3: History of Company – Question #3

In January 2023, the Myonex Facility Manager on file with the Alaska Board of Pharmacy unexpectedly submitted her resignation, effective January 13, 2023. Myonex quickly began taking steps to identify and install an appropriate replacement prior to its outgoing Facility Manager's effective resignation date so as to ensure uninterrupted continuity of operations. Myonex notified the Alaska Board of Pharmacy of the change in designated representative by email on February 2, 2023. Myonex submitted the formal notification to Alaska Board of Pharmacy on February 15, 2023. At the time that it submitted its formal notification on February 15, Myonex also had a name change application pending before the Alaska Board of Pharmacy (Myonex underwent a legal entity conversion from Myonex, Inc. to Myonex, LLC effective as of December 31, 2022), which was approved on March 23, 2023 and issued under a new license number. In April 2023, Myonex was advised by the Alaska Board of Pharmacy that it had to submit a new application for the change in Facility Manager under the new name and license number, which Myonex submitted on April 20, 2023.

Myonex, LLC received notice from the Board that it was placing the matter under investigation. On May 9, 2024, the Board issued to Myonex a Non-Disciplinary Letter of Advisement.

Gregory T Lamm

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SAVEWAY COMPOUNDING PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SAVEWAY COMPOUNDING PHARMACY, LLC" WAS FORMED ON THE THIRD DAY OF JULY, A.D. 2001.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3411401 8300

SR# 20241184518

Authentication: 203121470

Date: 03-27-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

SAVEWAY
COMPOUNDING
PHARMACY, LLC

Saveway Compounding Pharmacy, LLC

Officers / Owners List

FEIN # 51-0410858

State of Incorporation: Delaware

OFFICERS:

James Lovett – CEO
100 Progress Drive
Horsham, PA 19044

Gregory Lavin – CFO
100 Progress Drive
Horsham, PA 19044

Michael Cohen – Executive Chairman
100 Progress Drive
Horsham, PA 19044

Robert Cohen – President
100 Progress Drive
Horsham, PA 19044

OWNER / MEMBER:

Myonex, LLC – Sole Member of Saveway Compounding Pharmacy, LLC (100% Ownership of Saveway Compounding Pharmacy, LLC)
100 Progress Drive
Horsham, PA 19044

NOT TRANSFERABLE

STATE OF DELAWARE
DIVISION OF PROFESSIONAL REGULATION

CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

PROFESSIONAL LICENSE

PROFESSION:	Pharmacy
LICENSE TYPE:	Pharmacy - Retail
LICENSE NUMBER:	A3-0011089
LICENSE STATUS:	Active
ISSUE DATE:	03/07/2024
EXPIRATION DATE:	09/30/2024
ISSUED TO:	Saveway Compounding Pharmacy, LLC.
PHYSICAL ADDRESS:	31 ALBE DRIVE NEWARK DE 19702
SIGNATURE:	

THIS CERTIFIES THAT THE PERSON NAMED IS HEREBY LICENSED TO
CONDUCT OR ENGAGE IN THE PROFESSION INDICATED ABOVE.
THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF DELAWARE

Department of State
Division of Professional Regulation
Our mission is to credential qualified professionals to ensure the protection of the public's health, safety, and welfare

Online Services

The Division of Professional Regulation is proud of our professional and responsive customer service. To receive renewal notices and other critical information, be sure to keep your professional license contact information up-to-date.

To manage your license, log into DELPROS. Visit our web site at dpr.delaware.gov for essential reference information and 24/7 access to online services.

Can't find what you need online? Send an email to customerservice.dpr@delaware.gov and let us know what you need.

License Look Up

Disclaimer: DELPROS online verifications are considered ***primary source verifications* and are free of charge. These online license verifications contain real time information from our DELPROS licensure database.

Jul 18, 2024 09:06 EST

Saveway Compounding Pharmacy, LLC.

Status	Active
Profession	Pharmacy
Type	Pharmacy - Retail
Application Type	Initial Application
License/Application/Approval Number	A3-0011089
Issue Date	03/07/2024
Expiration Date	09/30/2024
Street Address	31 ALBE DRIVE
City	NEWARK
State	DE
Zipcode	19702
Discipline	No

Discipline Information and Public Documents:

If the licensee above has been disciplined, disciplinary actions cited in the diseiplinary order, consent agreement, or reprimand appear below. To view the law, click Delaware Code. To view a profession's Rules and Regulations, click dpr.delaware.gov, select the profession and then click Rules and Regulations under Information on the left menu bar.

2246

Current EST Time is **Jul 18, 2024 09:06 EST**

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS3957466	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-28-2024

SAVEWAY COMPOUNDING PHARMACY, LLC
31 ALBE DR
NEWARK, DE 197021360

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS3957466	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-28-2024

SAVEWAY COMPOUNDING PHARMACY, LLC
31 ALBE DR
NEWARK, DE 197021360

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Saveway Compounding Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 31 Albe Drive

City Newark State DE Zip 19702

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 3023695520 Website www.savewaypharmacy.com

Licensing Company Email license@savewaypharmacy.com

Section 2: Personal Information

First Pradeep Middle _____ Last Chilakapati

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Albe Drive

City Newark State DE Zip 19702

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Gulbarga University		09/25 - 01/2000	
Address	**City**	**State**	**Zip**
Sedam Road, Jnana Ganga, Kalaburagi, Karnataka		India	585106
Diploma/Degree obtained, if any			
Foreign Pharmacy Degree			

School Name		From - To (MM/YY – MM/YY)	
Vikas Junior College		06/93 - 04/95	
Address	**City**	**State**	**Zip**
ITC Road	Guntur	India	522601
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
V.S. St. John's Higher Secondary School		06/82 - 04/93	
Address	**City**	**State**	**Zip**
		India	521101
Diploma/Degree obtained, if any			
Davaji Gudem Road, Sri Nagar Colony, Gannavaram, Andhra Pradesh			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/18 - Present	[redacted]Rosenberger Drive	Middletown	DE	19709
03/11 - 10/18	[redacted]Scarecrow CT	Hockessin	DE	19707
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Saveway Compounding Pharmacy, LLC			10/15 - Present	
Business Address		**City**	**State**	**Zip**
31 Albe Drive		Newark	DE	19702
Phone	**Title**		**Number of Employed Hours**	
3023695520	PIC		40 hrs weekly	
Description of Duties				
Pharmacist - In - Charge				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Pradeep Chilakapati, **certify that as the designated representative for**

Saveway Compounding Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PC I am at least 21 years of age;
3. PC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

PRADEEP CHILAKAPATI
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07-17-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PRADEEP CHILAKAPATI
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07-17-2024
Date

Please have this section completed in the presence of a Notary Public.

State of DELAWARE, ss. County of NEW CASTLE

I, PRADEEP CHILAKAPATI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07-17-2024
Date

Subscribed and Sworn to before me this 17th day of July 2024.

Notary Public Signature

BRENDA L. POLAND
Notary Public
State of Delaware
My Commission Expires On
October 02, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Saveway Compounding Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 3023695520 Website: www.savewaypharmacy.com

Licensing Company Email: license@savewaypharmacy.com

Section 2: Personal Information

First: James Middle: Whitfield Last: Lovett

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Albe Drive

City: Newark State: DE Zip: 19702

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwestern University		09/82 - 06/85	
Address	**City**	**State**	**Zip**
Sheridan Road	Evanston	IL	
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
McCallie School		09/80 - 06-82	
Address	**City**	**State**	**Zip**
McCallie Avenue	CHattanooga	TN	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Owensboro High School		09/78 - 06/80	
Address	**City**	**State**	**Zip**
Frederica Street	Owensboro	KY	
Diploma/Degree obtained, if any			
No Degree (Transferred After Sophomore Year)			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - Present	[redacted]Bleddyn Lane	Ardmore	PA	19003
04/14 - 12/20	[redacted]brahams Lane	Villanova	PA	19085

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Myonex, LLC			02/17 - Present
Business Address	**City**	**State**	**Zip**
100 Progress Drive	Horsham	PA	19044
Phone	**Title**		
6102333300	CEO		

Description of Duties

Help develop and execute strategic vision and direction for the company.
Responsible for all operations of the company.

Business Name			From - To (MM/YY – MM/YY)
Aspen Strategic Advisory, LLC			2016 -01/17
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	Founder and CEO		

Description of Duties

Provided business strategy and law department management insight at this boutique consulting practice.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/9/2024	5/9/2024	AK	Anchorage	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2023-000345		State of Alaska Board of Pharmacy		
Reason/Charge				
Non-Disciplinary Letter of Advisement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of Alaska Board of Pharmacy			Non-Disciplinary Letter of Advisement	
Name of Business/Industry/Entity				
Myonex, LLC				

Provide explanation below:

In January 2023, the Myonex Facility Manager on file with the Alaska Board of Pharmacy unexpectedly submitted her resignation, effective January 13, 2023. Myonex quickly began taking steps to identify and install an appropriate replacement prior to its outgoing Facility Manager's effective resignation date so as to ensure uninterrupted continuity of operations. Myonex notified the Alaska Board of Pharmacy of the change in designated representative by email on February 2, 2023. Myonex submitted the formal notification to Alaska Board of Pharmacy on February 15, 2023. At the time that it submitted its formal notification on February 15, Myonex also had a name change application pending before the Alaska Board of Pharmacy (Myonex underwent a legal entity conversion from Myonex, Inc. to Myonex, LLC effective as of December 31, 2022), which was approved on March 23, 2023 and issued under a new license number. In April 2023, Myonex was advised by the Alaska Board of Pharmacy that it had to submit a new application for the change in Facility Manager under the new name and license number, which Myonex submitted on April 20, 2023.

Myonex, LLC received notice from the Board that it was placing the matter under investigation. On May 9, 2024, the Board issued to Myonex a Non-Disciplinary Letter of Advisement.

James Lovett is an officer of Myonex, LLC.

Original Signature (electronic, copies or stamps not accepted)

18 July 2024
Date

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Toll free fax: 907.269.8195

May 9, 2024

Email:
christen.tuttle@troutman.com

Myonex, LLC
Attn: Christen Tuttle, attorney representative
100 PROGRESS DRIVE
HORSHAM, PA 19044

Re: State of Alaska Board of Pharmacy- Case No.: 2023-000345

NON-DISCIPLINARY LETTER OF ADVISEMENT

Dear Ms. Tuttle,

This letter is to advise Myonex, LLC that the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) and the Alaska Board of Pharmacy (Board) have completed the investigation of the licensing allegations filed against Myonex, LLC.

After a thorough review by a licensed Board Member, it was determined Myonex, LLC submitted a change of Facility Manager form on April 20, 2023, for a change that occurred on January 16, 2023, which was past the 10-day reporting requirement, Myonex LLC was in violation of the following Alaska regulation: 12 AAC 52.635(a).

The Board Member determined a violation was present, and as a result, the Board placed this matter under investigation; however, it was their opinion that Myonex, LLC's actions did not rise to the level requiring formal disciplinary action against their license, and the appropriate disposition for this matter is to issue Myonex, LLC this **Non-Disciplinary Letter of Advisement.**

This letter advises Myonex, LLC to **be aware of all Alaska Board of Pharmacy statutory and regulatory requirements to practice in the state of Alaska and to disclose all future changes in facility managers/designated representatives within the now 30 day requirement after the change occurs.**

This letter will be retained in our files and is evidence of the Board's concern and the fact Myonex, LLC has been notified of the requirement under Alaska Statute 08.80 and Regulation 12 AAC 52 to abide by all laws governing their license.

This investigation is now closed. This letter is non-disciplinary and, therefore, cannot be appealed. This document will not be posted on the public website, however, it is a public document and may be released to an inquirer through an Alaska Public Records Request. Because Myonex, LLC was under official investigation, they, the Board, or the Division may be required to report that information on future license applications, including their Alaska renewal.

Thank you for your cooperation in this matter. Please feel free to contact me directly via email holly.handley@alaska.gov or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tammie Lovato

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 July 2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ _____

Original Signature **Date**

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Saveway Compounding Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 3023695520 Website: www.savewaypharmacy.com

Licensing Company Email: license@savewaypharmacy.com

Section 2: Personal Information

First: Robert Middle: Allen Last: Cohen

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Albe Drive

City: Newark State: DE Zip: 19702

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy and Science			09/62-06/67	
Address	**City**		**State**	**Zip**
600 South 43rd Street	Philadelphia		PA	19104
Diploma/Degree obtained, if any				
B.S., Pharmacy				

School Name			From - To (MM/YY – MM/YY)	
A.D. Eisenhower High School			09/59-06/62	
Address	**City**		**State**	**Zip**
1601 Markley Street	Norristown		PA	19401
Diploma/Degree obtained, if any				
High School Diploma, Academic				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23-Present	[redacted] Fox Hound Drive	Lafayette Hill	PA	19444
12/08-11/23	[redacted] Mahogany Way	Lansdale	PA	19446
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Myonex, LLC			From - To (MM/YY – MM/YY): 1987 - Present	
Business Address: 100 Progress Drive		City: Horsham	State: PA	Zip: 19044
Phone: 6102333300	Title: President			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/28/2008	10/15/2008	PA	Norristown	Montgomery
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2008-02221		Montgomery County		
Reason/Charge				
Complaint Civil Action				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Norman Watson			Lawsuit	
Name of Business/Industry/Entity				
Myers Drug Store, inc.				

Provide explanation below:

Mr. Watson claimed to have slipped and fell, causing injury, at a property owned by Robert Cohen, where Myers Drug Store, inc. was operating, a business he was a partial owner in as well. The case was settled out of court.

Robert Cohen
Original Signature (electronic, copies or stamps not accepted)

07/18/2024
Date

Case #2008-02221

Case Number	2008-02221
Commencement Date	1/28/2008
Last Filing Date	10/15/2008
Days Open	261
Case Type	Complaint Civil Action
PFA Number	
Caption Plaintiff	WATSON, NORMAN
Caption Defendant	MYERS DRUG STORE INC
Lis Pendens Indicator	No
Status	6 - CLOSED
Judge	ARTHUR TILSON
Remarks	
Sealed	No
Interpreter Needed	

Plaintiffs

Name	Address	Country	Counsel	Notify	Sequence	Status
WATSON, NORMAN	2136 FITZWATER ST PHILA, PA 19146 UNITED STATES	UNITED STATES	HIMMEL, PAUL B	Yes	1	

Defendants

Name	Address	Country	Counsel	Notify	Sequence	Status
MYERS DRUG STORE INC	328 DEKALB ST NORRISTOWN, PA 19401 UNITED STATES	UNITED STATES	GOLDBERG, JOSEPH MOORE, SYREETA JOYCE	No	1	
COHEN, ROBERT A	3217 POLK ST NORRISTOWN, PA 19403 UNITED STATES	UNITED STATES	SCARICAMAZZA, ANGELO L JR	No	2	

Docket Entries

Seq.		Filing Date	Docket Type	Docket Text	Sealed	Filing ID
0		1/28/2008	Complaint Civil Action		No	6939964
1		1/28/2008	Civil Cover Sheet		No	6939993
2		2/1/2008	(Internal Use Only) Served	ROBERT A COHEN ON 1-31-08	No	6946226
3		2/5/2008	(Internal Use Only) Served	MYERS DRUG STORE ON 1-30-08	No	6949869
4		2/13/2008	Praec for Substitution of	VERIFICATION IN COMPLT	No	6959328
5		4/7/2008	Entry of Appearance	OF ANGELO L SCARICAMAZZA JR FOR DEFT ROBERT A COHEN	No	7011258
6		4/7/2008	Answer & New Matter by	DEFT ROBERT A COHEN	No	7011263
7		4/7/2008	Certificate of Service	OF PLEADING ON 4/4/08	No	7011268
8		4/17/2008	Entry of Appearance	OF JOSEPH GOLDBER & SYREETA J PEAKE FORT DEFT MYERS DRUG STORE INC	No	7022841
9		4/29/2008	Answer & New Matter by	DEFT MYERS DRUG STORE INC	No	7034377
10		4/29/2008	Certificate of Service	OF ANS & NEW MATTER ON 4/19/08	No	7034378
11		5/20/2008	Reply to New Matter	BY PLTF	No	7057485
12		5/29/2008	Certificate Pre Requisite Rule 4009.22		No	7065661
13		7/16/2008	Certificate Pre Requisite Rule 4009.22		No	7114232
14		10/15/2008	Praecipe to Discontinue For Cases Filed 1993 & Above		No	7207149

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This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/20/2024	pending	PA	Philadelphia	Philadelphia
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
240602268		Philadelphia County Court of Common Pleas Civil Trial Division		
Reason/Charge				
Complaint Civil Action				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Carey Cunningham Sr.			Lawsuit	
Name of Business/Industry/Entity				
Myonex Holdings, LLC				

Provide explanation below:

Myonex Holdings, Inc. (incorrectly named in the complaint as Myonex Holdings, LLC) was named as a defendant in a slip and fall lawsuit related to an incident that occurred at Myonex's property in Horsham, PA in August 2023. Robert Cohen is an owner and officer of Myonex Holdings, Inc. Myonex is defending the lawsuit which remains pending.

Robert Cohen

Original Signature (electronic, copies or stamps not accepted)

07/18/2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/9/2024	5/9/2024	AK	Anchorage	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2023-000345		State of Alaska Board of Pharmacy		
Reason/Charge				
Non-Disciplinary Letter of Advisement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of Alaska Board of Pharmacy			Non-Disciplinary Letter of Advisement	
Name of Business/Industry/Entity				
Myonex, LLC				

Provide explanation below:

In January 2023, the Myonex Facility Manager on file with the Alaska Board of Pharmacy unexpectedly submitted her resignation, effective January 13, 2023. Myonex quickly began taking steps to identify and install an appropriate replacement prior to its outgoing Facility Manager's effective resignation date so as to ensure uninterrupted continuity of operations. Myonex notified the Alaska Board of Pharmacy of the change in designated representative by email on February 2, 2023. Myonex submitted the formal notification to Alaska Board of Pharmacy on February 15, 2023. At the time that it submitted its formal notification on February 15, Myonex also had a name change application pending before the Alaska Board of Pharmacy (Myonex underwent a legal entity conversion from Myonex, Inc. to Myonex, LLC effective as of December 31, 2022), which was approved on March 23, 2023 and issued under a new license number. In April 2023, Myonex was advised by the Alaska Board of Pharmacy that it had to submit a new application for the change in Facility Manager under the new name and license number, which Myonex submitted on April 20, 2023.

Myonex, LLC received notice from the Board that it was placing the matter under investigation. On May 9, 2024, the Board issued to Myonex a Non-Disciplinary Letter of Advisement.

Robert Cohen is an owner and officer of Myonex, LLC.

Robert Cohen
Original Signature (electronic, copies or stamps not accepted)

07/18/2024
Date

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Toll free fax: 907.269.8195

May 9, 2024

Email:
christen.tuttle@troutman.com

Myonex, LLC
Attn: Christen Tuttle, attorney representative
100 PROGRESS DRIVE
HORSHAM, PA 19044

Re: State of Alaska Board of Pharmacy- Case No.: 2023-000345

NON-DISCIPLINARY LETTER OF ADVISEMENT

Dear Ms. Tuttle,

This letter is to advise Myonex, LLC that the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) and the Alaska Board of Pharmacy (Board) have completed the investigation of the licensing allegations filed against Myonex, LLC.

After a thorough review by a licensed Board Member, it was determined Myonex, LLC submitted a change of Facility Manager form on April 20, 2023, for a change that occurred on January 16, 2023, which was past the 10-day reporting requirement, Myonex LLC was in violation of the following Alaska regulation: 12 AAC 52.635(a).

The Board Member determined a violation was present, and as a result, the Board placed this matter under investigation; however, it was their opinion that Myonex, LLC's actions did not rise to the level requiring formal disciplinary action against their license, and the appropriate disposition for this matter is to issue Myonex, LLC this **Non-Disciplinary Letter of Advisement.**

This letter advises Myonex, LLC to **be aware of all Alaska Board of Pharmacy statutory and regulatory requirements to practice in the state of Alaska and to disclose all future changes in facility managers/designated representatives within the now 30 day requirement after the change occurs.**

This letter will be retained in our files and is evidence of the Board's concern and the fact Myonex, LLC has been notified of the requirement under Alaska Statute 08.80 and Regulation 12 AAC 52 to abide by all laws governing their license.

This investigation is now closed. This letter is non-disciplinary and, therefore, cannot be appealed. This document will not be posted on the public website, however, it is a public document and may be released to an inquirer through an Alaska Public Records Request. Because Myonex, LLC was under official investigation, they, the Board, or the Division may be required to report that information on future license applications, including their Alaska renewal.

Thank you for your cooperation in this matter. Please feel free to contact me directly via email holly.handley@alaska.gov or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Cohen

Print Name (First, Last)

Robert Cohen

Original Signature (electronic, copies or stamps not accepted)

07/18/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Robert Cohen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robert Cohen

Original Signature

07/18/2024

Date

Subscribed and Sworn to before me this 18 day of JULY.

Rose Caffrey

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rose Caffrey, Notary Public
Montgomery County
My commission expires January 20, 2026
Commission number 1411602

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Saveway Compounding Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 3023695520 Website: www.savewaypharmacy.com

Licensing Company Email: license@savewaypharmacy.com

Section 2: Personal Information

First: Michael Middle: Allen Last: Cohen

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Albe Drive

City: Newark State: DE Zip: 19702

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh - Katz Graduate School of Business		07/92-08/93	
Address	**City**	**State**	**Zip**
3950 Roberto Clemente Drive	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
M.B.A.			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		08/88-04/92	
Address	**City**	**State**	**Zip**
4200 Fifth Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
B.S. Statistics			

School Name		From - To (MM/YY – MM/YY)	
Norristown High School		09/84-06/88	
Address	**City**	**State**	**Zip**
1900 Eagle Drive	Norristown	PA	19401
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/09-Present	[redacted] Morgan Road	Rydal	PA	19046
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Myonex, LLC			07/19-Present	
Business Address		**City**	**State**	**Zip**
100 Progress Drive		Horsham	PA	19044
Phone	**Title**			
6102333300	Executive Chairman			

Description of Duties

Provide strategic vision and direction for the company, manages sales and client focused departments, manages CEO, who is responsible for finance, HR, operations, logistics and quality.

Business Name			From - To (MM/YY – MM/YY)	
Myonex, LLC			03/01-07/19	
Business Address		**City**	**State**	**Zip**
100 Progress Drive		Horsham	PA	19044
Phone	**Title**			
6102333300	CEO			

Description of Duties

Ran company - oversaw all sales and operations for Myonex.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

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1/28/2008	10/15/2008	PA	Norristown	Montgomery
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2008-02221		Montgomery Country		
Reason/Charge				
Complaint Civil Action				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Norman Watson			Lawsuit	
Name of Business/Industry/Entity				
Myers Drug Store, inc.				

Provide explanation below:

Mr. Watson claimed to have slipped and fell, causing injury, at a property owned by Robert Cohen, where Myers Drug Store, inc. was operating. I was a partial owner of Myers Drug Store, inc. The case was settled out of court.

Original Signature (electronic, copies or stamps not accepted)

7/16/2024
Date

Case #2008-02221

Case Number	2008-02221
Commencement Date	1/28/2008
Last Filing Date	10/15/2008
Days Open	261
Case Type	Complaint Civil Action
PFA Number	
Caption Plaintiff	WATSON, NORMAN
Caption Defendant	MYERS DRUG STORE INC
Lis Pendens Indicator	No
Status	6 - CLOSED
Judge	ARTHUR TILSON
Remarks	
Sealed	No
Interpreter Needed	

Plaintiffs

Name	Address	Country	Counsel	Notify	Sequence	Status
WATSON, NORMAN	2136 FITZWATER ST PHILA, PA 19146 UNITED STATES	UNITED STATES	HIMMEL, PAUL B	Yes	1	

Defendants

Name	Address	Country	Counsel	Notify	Sequence	Status
MYERS DRUG STORE INC	328 DEKALB ST NORRISTOWN, PA 19401 UNITED STATES	UNITED STATES	GOLDBERG, JOSEPH MOORE, SYREETA JOYCE	No	1	
COHEN, ROBERT A	3217 POLK ST NORRISTOWN, PA 19403 UNITED STATES	UNITED STATES	SCARICAMAZZA, ANGELO L JR	No	2	

Docket Entries

Seq.		Filing Date	Docket Type	Docket Text	Sealed	Filing ID
0		1/28/2008	Complaint Civil Action		No	6939964
1		1/28/2008	Civil Cover Sheet		No	6939993
2		2/1/2008	(Internal Use Only) Served	ROBERT A COHEN ON 1-31-08	No	6946226
3		2/5/2008	(Internal Use Only) Served	MYERS DRUG STORE ON 1-30-08	No	6949869
4		2/13/2008	Praec for Substitution of	VERIFICATION IN COMPLT	No	6959328
5		4/7/2008	Entry of Appearance	OF ANGELO L SCARICAMAZZA JR FOR DEFT ROBERT A COHEN	No	7011258
6		4/7/2008	Answer & New Matter by	DEFT ROBERT A COHEN	No	7011263
7		4/7/2008	Certificate of Service	OF PLEADING ON 4/4/08	No	7011268
8		4/17/2008	Entry of Appearance	OF JOSEPH GOLDBER & SYREETA J PEAKE FORT DEFT MYERS DRUG STORE INC	No	7022841
9		4/29/2008	Answer & New Matter by	DEFT MYERS DRUG STORE INC	No	7034377
10		4/29/2008	Certificate of Service	OF ANS & NEW MATTER ON 4/19/08	No	7034378
11		5/20/2008	Reply to New Matter	BY PLTF	No	7057485
12		5/29/2008	Certificate Pre Requisite Rule 4009.22		No	7065661
13		7/16/2008	Certificate Pre Requisite Rule 4009.22		No	7114232
14		10/15/2008	Praecipe to Discontinue For Cases Filed 1993 & Above		No	7207149

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This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/20/2024	pending	PA	Philadelphia	Philadelphia
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
240602268		Philadelphia County Court of Common Pleas Civil Trial Division		
Reason/Charge				
Complaint Civil Action				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Carey Cunningham Sr.		Lawsuit		
Name of Business/Industry/Entity				
Myonex Holdings, LLC				

Provide explanation below:

Myonex Holdings, Inc. (incorrectly named in the complaint as Myonex Holdings, LLC) was named as a defendant in a slip and fall lawsuit related to an incident that occurred at Myonex's property in Horsham, PA in August 2023. Michael Cohen is an owner and officer of Myonex Holdings, Inc. Myonex is defending the lawsuit which remains pending.

Original Signature (electronic, copies or stamps not accepted)

7/16/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/9/2024	5/9/2024	AK	Anchorage	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2023-000345		State of Alaska Board of Pharmacy		
Reason/Charge				
Non-Disciplinary Letter of Advisement				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of Alaska Board of Pharmacy		Non-Disciplinary Letter of Advisement		
Name of Business/Industry/Entity				
Myonex, LLC				

Provide explanation below:

In January 2023, the Myonex Facility Manager on file with the Alaska Board of Pharmacy unexpectedly submitted her resignation, effective January 13, 2023. Myonex quickly began taking steps to identify and install an appropriate replacement prior to its outgoing Facility Manager's effective resignation date so as to ensure uninterrupted continuity of operations. Myonex notified the Alaska Board of Pharmacy of the change in designated representative by email on February 2, 2023. Myonex submitted the formal notification to Alaska Board of Pharmacy on February 15, 2023. At the time that it submitted its formal notification on February 15, Myonex also had a name change application pending before the Alaska Board of Pharmacy (Myonex underwent a legal entity conversion from Myonex, Inc. to Myonex, LLC effective as of December 31, 2022), which was approved on March 23, 2023 and issued under a new license number. In April 2023, Myonex was advised by the Alaska Board of Pharmacy that it had to submit a new application for the change in Facility Manager under the new name and license number, which Myonex submitted on April 20, 2023.

Myonex, LLC received notice from the Board that it was placing the matter under investigation. On May 9, 2024, the Board issued to Myonex a Non-Disciplinary Letter of Advisement.

Michael Cohen is an owner and officer of Myonex, LLC.

Original Signature (electronic, copies or stamps not accepted)

7/16/2024
Date

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Toll free fax: 907.269.8195

May 9, 2024

Email:
christen.tuttle@troutman.com

Myonex, LLC
Attn: Christen Tuttle, attorney representative
100 PROGRESS DRIVE
HORSHAM, PA 19044

Re: State of Alaska Board of Pharmacy- Case No.: 2023-000345

NON-DISCIPLINARY LETTER OF ADVISEMENT

Dear Ms. Tuttle,

This letter is to advise Myonex, LLC that the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) and the Alaska Board of Pharmacy (Board) have completed the investigation of the licensing allegations filed against Myonex, LLC.

After a thorough review by a licensed Board Member, it was determined Myonex, LLC submitted a change of Facility Manager form on April 20, 2023, for a change that occurred on January 16, 2023, which was past the 10-day reporting requirement, Myonex LLC was in violation of the following Alaska regulation: 12 AAC 52.635(a).

The Board Member determined a violation was present, and as a result, the Board placed this matter under investigation; however, it was their opinion that Myonex, LLC's actions did not rise to the level requiring formal disciplinary action against their license, and the appropriate disposition for this matter is to issue Myonex, LLC this **Non-Disciplinary Letter of Advisement.**

This letter advises Myonex, LLC to **be aware of all Alaska Board of Pharmacy statutory and regulatory requirements to practice in the state of Alaska and to disclose all future changes in facility managers/designated representatives within the now 30 day requirement after the change occurs.**

This letter will be retained in our files and is evidence of the Board's concern and the fact Myonex, LLC has been notified of the requirement under Alaska Statute 08.80 and Regulation 12 AAC 52 to abide by all laws governing their license.

This investigation is now closed. This letter is non-disciplinary and, therefore, cannot be appealed. This document will not be posted on the public website, however, it is a public document and may be released to an inquirer through an Alaska Public Records Request. Because Myonex, LLC was under official investigation, they, the Board, or the Division may be required to report that information on future license applications, including their Alaska renewal.

Thank you for your cooperation in this matter. Please feel free to contact me directly via email holly.handley@alaska.gov or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Cohen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/16/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Michael Cohen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/16/2024

Date

Subscribed and Sworn to before me this 16 day of JULY.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rose Caffrey, Notary Public
Montgomery County
My commission expires January 20, 2026
Commission number 1411602

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Saveway Compounding Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 3023695520 Website: www.savewaypharmacy.com

Licensing Company Email: license@savewaypharmacy.com

Section 2: Personal Information

First: Greg Middle: Thomas Last: Lavin

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Hickory Road

City: Plymouth Meeting State: PA Zip: 19462

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LaSalle College High School		09/89-06/93	
Address	**City**	**State**	**Zip**
8605 W. Cheltenham Ave.	Wyndmoor	PA	19038
Diploma/Degree obtained, if any			
High School Degree			

School Name		From - To (MM/YY – MM/YY)	
Boston College		09/93-05/97	
Address	**City**	**State**	**Zip**
140 Commonwealth Ave.	Chestnut Hill	MA	02467
Diploma/Degree obtained, if any			
Bachelors Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/11-	[redacted]Hickory Road	Plymouth Meeting	PA	19462
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Myonex, LLC			03/19 - Present
Business Address	**City**	**State**	**Zip**
100 Progress Drive	Horsham	PA	19044
Phone	**Title**		
610 233 3300	Chief Financial Officer		

Description of Duties

Chief Financial Officer overseeing all financial accounting, reporting, treasury, risk management and financial planning and analysis across the global Myonex organization.

Business Name			From - To (MM/YY – MM/YY)
QPS Holdings, LLC			01/15-03/19
Business Address	**City**	**State**	**Zip**
3 Innovation Way	Newark	DE	19711
Phone	**Title**		
512 350 2827	Chief Financial Officer		

Description of Duties

Chief Financial Officer overseeing all financial accounting, reporting, treasury, risk management and financial planning and analysis across the global QPS organization.

Business Name			From - To (MM/YY – MM/YY)
Strategic Distribution, Inc.			02/12-01/15
Business Address	**City**	**State**	**Zip**
1414 Radcliffe Street #300	Bristol	PA	19007
Phone	**Title**		
(800) 322-2644	Director Finance		

Description of Duties

Director Finance overseeing financial reporting, treasury, risk management and financial planning across the global SDI organization.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/20/2024	pending	PA	Philadelphia	Philadelphia

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
240602268	Philadelphia County Court of Common Pleas Civil Trial Division

Reason/Charge
Complaint Civil Action

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Carey Cunningham Sr.	Lawsuit

Name of Business/Industry/Entity
Myonex Holdings, LLC

Provide explanation below:

Myonex Holdings, Inc. (incorrectly named in the complaint as Myonex Holdings, LLC) was named as a defendant in a slip and fall lawsuit related to an incident that occurred at Myonex's property in Horsham, PA in August 2023. Greg Lavin is an officer of Myonex Holdings, Inc. Myonex is defending the lawsuit which remains pending.

Original Signature (electronic, copies or stamps not accepted)

16 July 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
5/9/2024	5/9/2024	AK	Anchorage	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2023-000345		State of Alaska Board of Pharmacy		
Reason/Charge				
Non-Disciplinary Letter of Advisement				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of Alaska Board of Pharmacy		Non-Disciplinary Letter of Advisement		
Name of Business/Industry/Entity				
Myonex, LLC				

Provide explanation below:

In January 2023, the Myonex Facility Manager on file with the Alaska Board of Pharmacy unexpectedly submitted her resignation, effective January 13, 2023. Myonex quickly began taking steps to identify and install an appropriate replacement prior to its outgoing Facility Manager's effective resignation date so as to ensure uninterrupted continuity of operations. Myonex notified the Alaska Board of Pharmacy of the change in designated representative by email on February 2, 2023. Myonex submitted the formal notification to Alaska Board of Pharmacy on February 15, 2023. At the time that it submitted its formal notification on February 15, Myonex also had a name change application pending before the Alaska Board of Pharmacy (Myonex underwent a legal entity conversion from Myonex, Inc. to Myonex, LLC effective as of December 31, 2022), which was approved on March 23, 2023 and issued under a new license number. In April 2023, Myonex was advised by the Alaska Board of Pharmacy that it had to submit a new application for the change in Facility Manager under the new name and license number, which Myonex submitted on April 20, 2023.

Myonex, LLC received notice from the Board that it was placing the matter under investigation. On May 9, 2024, the Board issued to Myonex a Non-Disciplinary Letter of Advisement.

Greg Lavin is an officer of Myonex, LLC.

Original Signature (electronic, copies or stamps not accepted)

16 July 2024
Date

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Toll free fax: 907.269.8195

May 9, 2024

Email:
christen.tuttle@troutman.com

Myonex, LLC
Attn: Christen Tuttle, attorney representative
100 PROGRESS DRIVE
HORSHAM, PA 19044

Re: State of Alaska Board of Pharmacy- Case No.: 2023-000345

NON-DISCIPLINARY LETTER OF ADVISEMENT

Dear Ms. Tuttle,

This letter is to advise Myonex, LLC that the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) and the Alaska Board of Pharmacy (Board) have completed the investigation of the licensing allegations filed against Myonex, LLC.

After a thorough review by a licensed Board Member, it was determined Myonex, LLC submitted a change of Facility Manager form on April 20, 2023, for a change that occurred on January 16, 2023, which was past the 10-day reporting requirement, Myonex LLC was in violation of the following Alaska regulation: 12 AAC 52.635(a).

The Board Member determined a violation was present, and as a result, the Board placed this matter under investigation; however, it was their opinion that Myonex, LLC's actions did not rise to the level requiring formal disciplinary action against their license, and the appropriate disposition for this matter is to issue Myonex, LLC this **Non-Disciplinary Letter of Advisement.**

This letter advises Myonex, LLC to **be aware of all Alaska Board of Pharmacy statutory and regulatory requirements to practice in the state of Alaska and to disclose all future changes in facility managers/designated representatives within the now 30 day requirement after the change occurs.**

This letter will be retained in our files and is evidence of the Board's concern and the fact Myonex, LLC has been notified of the requirement under Alaska Statute 08.80 and Regulation 12 AAC 52 to abide by all laws governing their license.

This investigation is now closed. This letter is non-disciplinary and, therefore, cannot be appealed. This document will not be posted on the public website, however, it is a public document and may be released to an inquirer through an Alaska Public Records Request. Because Myonex, LLC was under official investigation, they, the Board, or the Division may be required to report that information on future license applications, including their Alaska renewal.

Thank you for your cooperation in this matter. Please feel free to contact me directly via email holly.handley@alaska.gov or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Greg Lavin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/16/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Greg Lavin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/16/2024

Date

Subscribed and Sworn to before me this 16 day of JULY.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rose Caffrey, Notary Public
Montgomery County
My commission expires January 20, 2026
Commission number 1411602

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Saveway Compounding Pharmacy, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 31 Albe Drive

City: Newark State: DE Zip: 19702

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 3023695520 Toll Free # (NAC 639.708, NRS 639.23286): 8772858143

Fax: 3023695853 Contact Email: license@savewaypharmacy.com

Website: www.savewaypharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Pradeep Chilakapati

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22784

Name of Person with direct knowledge of compounding procedures: Pradeep Chilakapati

Email of Person with direct knowledge of compounding procedures: license@savewaypharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 3023695520

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
WE WILL SHIP COMPOUNDED MEDICATIONS INTO NEVADA BASED ON REQUEST. SINCE THIS IS NEW LICENSURE, WE DO NOT HAVE A HISTORY OF PREPARATIONS SPECIFIC TO NEVADA. WE CAN SUPPLY A LIST OF OUR TOP 100 COMPOUNDED PREPARATIONS IF THAT WOULD BE HELPFUL.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?
Name: N/A
Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
SEE ATTACHED SOP 4.016 FINAL CHECK--SECTION 9.5.3.6.7 VISUAL INSPECTION

8. How often do you perform glove fingertip and medial fill testing?

3 GFTs INITIALLY AND THEN 1 GFT QUARTERLY FOR GOWNING QUALIFICAITON AND QTRLY MEDIA FILL FOR PERSONNEL MONITORING. 1 GFT AND SURFACE SAMPLE PER COMPOUNDER PER DAY OF ACTIVITY

9. What is your policy if an employee fails a glove fingertip or media-fill test?

COMPLETE RETRAINING OF FAILED PERSONNEL. PERSONNEL MAY NOT COMPOUND INDEPENDENTLY UNTIL RETESTED WITH PASSING RESULTS.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

READING OF SOPs SPECIFIC TO THEIR EXPECTED DUTIES, ASSIGNED LEARNING FROM CRITICAL POINT, ASEPTIC TECHNIQUE AND CLEAN ROOM BEHAVIOR IS TAUGHT AND THEN DEMONSTRATED, WRITTEN TESTING, SHADOW SENIOR PERSONNEL. TASKS ARE DEMONSTRATED TO NEW HIRE, THEN NEW HIRE PERFORMS TASK UNDER DIRECT SUPERVISION BEFORE PERFORMING INDEPENDENTLY.
ANNUAL TRAINING INCLUDES WRITTEN TESTS, VISUAL OBSERVATION AND DOCUMENTATION OF TASKS, HD TRAINING, SAFETY TRAINING, EVALUATION OF CORE COMPETENCIES, ASSIGNED CRITICAL POINT LEARNING.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

PECs ARE CLEANED FROM TOP TO BOTTOM BACK TO FROM STARTING WITH THE CLEANEST AREA AND WORKING FORWARD DAILY. STERILE ISOPROPYL ALCOHOL 70% IS USED TO CLEAN THE PEC IMMEDIATLEY PRIOR TO USE AND BETWEEN EACH CSP. PREEMPT IS USED AT THE END OF EVERY DAY.
WEEKLY CLEANING OF PECs AND SECs IS PERFORMED WITH PERIDOX RTU FOLLOWED BY STERILE IPA70% TO REMOVE RESIDUE AND INCLUDES ALL HORIZONTAL WORK SURFACES, HIGH TOUCH AREAS, EQUIPMENT, CART TOPS, TABLES, ETC.
FLOORS OF ENTIRE COMPOUNDING SUITE ARE CLEANED DAILY WITH HYPOCHLOR 0.525% AND WITH PERIDOX FOLLOWED BY STERILE WATER FOR IRRIGATION TO RINSE MONTHLY.
THE ENTIRE SUITE OF ROOMS, INCLUDING ALL SHELVES AND BINS, WORK AREAS, TABLES, CARTS,AND PECs, ETC ARE EMPTIED AND CLEANED WITH PERIDOX FOLLOWED BY IPA.

12. Who performs the sterile compounding process at your facility?

EXPERTLY TRAINED CERTIFIED PHARMACY TECHNICIANS AND PHARMACIST

13. Who is responsible and accountable for the sterile compounding process at your facility?

BRENDA POLAND IS THE SENIOR QUALITY MANAGER
CAITLIN KOMM, PHARMD IS THE STAFF PHARMACIST AND DEPARTMENT MANAGER ASSIGNED TO THE STERILE DEPARTMENT

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

IT DEPENDS ON THE PREPARATION BUT ALL COMPOUNDED MEDICATIONS ARE SHIPPED USING PACKAGING MATERIALS TO MAINTAIN THE INTEGRITY, STERILITY, STABILITY AND OVERALL QUALITY OF THE PREPARATION.
SEE ATTACHED SOP 4.024 SHIPPING AND VALIDATION OF COMPOUNDED PREPARATIONS

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?

WE HAVE A CLASS II A2 BIOLOGICAL SAFETY CABINET LOCATED IN A NEGATIVE PRESSURE ISO 7 BUFFER ROOM.

2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☑ Yes	☐ No

7. If yes, list the name of the device:

WHEN NEEDED WE USE ONGUARD CSTD BY BRAUN

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

ALL HAZARDOUS DRUG SUBSTANCES ARE CLEARLY LABELED AS SUCH AND PACKAGED SECURELY IN IDENTIFYING PACKAGING. PATIENTS ARE OFFERED COUNSELING ON THE SAFE USE OF, RISK ASSOCIATED, AND PROPER DISPOSAL OF HDs.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

READING OF SOPs SPECIFIC TO THEIR EXPECTED DUTIES AND THE HANDLING OF HDs, ASSIGNED LEARNING FROM CRITICAL POINT, ASEPTIC TECHNIQUE AND CLEAN ROOM BEHAVIOR IS TAUGHT AND THEN DEMONSTRATED, WRITTEN TESTING, SHADOW SENIOR PERSONNEL. TASKS ARE DEMONSTRATED TO NEW HIRE, THEN NEW HIRE PERFORMS TASK UNDER DIRECT SUPERVISION BEFORE PERFORMING INDEPENDENTLY.

ANNUAL TRAINING INCLUDES WRITTEN TESTS, VISUAL OBSERVATION AND DOCUMENTATION OF TASKS, HD TRAINING, SAFETY TRAINING, EVALUATION OF CORE COMPETENCIES, ASSIGNED CRITICAL POINT LEARNING.

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

SEE ATTACHED LIST OF STERILE COMPOUNDS MADE IN 30 DAYS

2. What sterilization methods are utilized at your facility?

ASEPTIC FILTRATION
TERMINAL STERILIZATION VIA AUTOCLAVE OR DRY HEAT OVEN

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

BIs ARE PLACED IN EVERY AUTOCLAVE OR DRY HEAT CYCLE CONTAINING A CSP FOR TERMINAL STERILIZATION. THE BI IS THEN TRANSFERRED TO THE CLEANROOM AND ASEPTICALLY PLACED INTO A STERILE VIAL OF GROWTH MEDIA AND THEN INCUBATED AND MONITORED DAILY AND THE RESULTS RECORDED

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRENDA POLAND
Name of Person who Completed the Form

QUALITY MANAGER
Title

Signature (copies or stamps not accepted)

07-17-2024
Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/19/2024	10 ML	20241906@12	8/3/2024	Finalized: ☐ Temp Log: ☐ ☑
ACETYLCYSTEINE OPHTH (PF) 10% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $60.00	Last modified: 6/19/2024	by: BRENDA	
Remaining	10			
Note	rx 6073003- KC / br 1			
7/3/2024	10 ML	20240307@5	8/17/2024	Finalized: ☐ Temp Log: ☐ ☑
ACETYLCYSTEINE OPHTH (PF) 10% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $60.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	10			
Note	rx 6065538- MB / br 1			
7/16/2024	10 ML	20241607@81	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑
ACETYLCYSTEINE OPHTH (PF) 10% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $60.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	10			
Note	rx 6057724- am / br 5			
7/8/2024	10 ML	20240807@96	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
ACETYLCYSTEINE SOLN 10% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $60.00	Last modified: 7/9/2024	by: BRENDA	
Remaining	10			
Note	rx 6074403- MB/ br 1			
7/11/2024	30 ML	20241107@22	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑
ACETYLCYSTEINE SOLUTION 20% INHALATION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $65.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	30			
Note	rx 6074870- mb/ br 1			
7/12/2024	55 ML	20241207@14	1/8/2025	Finalized: ☐ Temp Log: ☐ ☑
ACL MOXIFLOXACIN HCL+BROMFENAC NA+DEXAMETHASONE+PVP 2.5%+0.2%+0.006%+0.5% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	55			
Note	stock- AM / br 2			
6/24/2024	10 ML	20242406@27	7/24/2024	Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 1000MCG/0.5ML GEL				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $900.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	10			
Note	6073014- KC / BR 1			

Date made	Qty made & units	Lot number	Beyond use date	Active
7/12/2024	8 ML	20241207@7	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 10 MCG/ML INJECTABLE				NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $112.00 Last modified: 7/12/2024 by: BRENDA
Remaining 8

Note rx 6046283- AM/_MB__/ br 1___

6/19/2024 8 ML 20241906@1 8/3/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 20 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $144.00 Last modified: 6/19/2024 by: BRENDA
Remaining 8

Note rx 6072862- am/mb/br 1____

7/1/2024 8 ML 20240107@11 8/15/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 20 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $144.00 Last modified: 7/1/2024 by: BRENDA
Remaining 8

Note rx 6069943- mb/____/ br 1____

7/9/2024 15 ML 20240907@24 8/23/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 20 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $270.00 Last modified: 7/9/2024 by: BRENDA
Remaining 15

Note rx 6058186+ stock- MB/ br 1

7/1/2024 20 ML 20240107@10 8/15/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 40 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $300.00 Last modified: 7/1/2024 by: BRENDA
Remaining 20

Note 2 rx + stock- mb/____/ br 1____

7/1/2024 7 ML 20240107@35 8/15/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 40 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $90.00 Last modified: 7/1/2024 by: BRENDA
Remaining 7

Note rx 6072757- cmk

7/16/2024 30 ML 20241607@5 8/30/2024 Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 40 MCG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $450.00 Last modified: 7/16/2024 by: BRENDA
Remaining 30

Note stock+ rx 6071444- mb/am____/ br 1__-

Date made	Qty made & units	Lot number	Beyond use date	Active
7/12/2024	20 ML	20241207@12	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑
ALPROSTADIL 40 MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $300.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	20			
Note	stock- am/ MB / br 1			
6/26/2024	190 ML	20242606@7	7/26/2024	Finalized: ☐ Temp Log: ☐ ☑
AMIKACIN INHALATION 250 MG/3 ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $316.67	Last modified: 6/26/2024	by: BRENDA	
Remaining	190			
Note	rx 6065727- MB / br 1			
6/20/2024	260 ML	20242006@17	6/30/2024	Finalized: ☐ Temp Log: ☐ ☑
AMPHOTERICIN B IN OPTISOL GS 2.5 MCG/ML VIAL				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	260			
Note	altruvison- MB /br 1			
7/3/2024	300 ML	20240307@2	7/13/2024	Finalized: ☐ Temp Log: ☐ ☑
AMPHOTERICIN B IN OPTISOL GS 2.5 MCG/ML VIAL				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	300			
Note	altruvison- MB / br 1			
6/27/2024	80 ML	20242706@3	7/7/2024	Finalized: ☐ Temp Log: ☐ ☑
AMPHOTERICIN B IN OPTISOL GS 2.5 MCG/ML VIAL				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	80			
Note	altruvision- MB / br 1			
7/11/2024	200 ML	20241107@28	7/21/2024	Finalized: ☐ Temp Log: ☐ ☑
AMPHOTERICIN B IN OPTISOL GS 2.5 MCG/ML VIAL				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	200			
Note	altruvision- MB/ br 1			
6/17/2024	6 ML	20241706@56	8/1/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $70.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	6			
Note	stock+ rx 6060151- cmk			

Date made	Qty made & units	Lot number	Beyond use date	Active
6/18/2024	60 ML	20241806@64	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $660.00	Last modified: 6/19/2024	by: BRENDA	
Remaining	60			
Note	stock+ 2 rx- AM / br 2			
7/3/2024	50 ML	20240307@15	8/17/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $550.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	50			
Note	stock- MB/br 1			
6/26/2024	8 ML	20242606@6	8/10/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.02% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $90.00	Last modified: 6/26/2024	by: BRENDA	
Remaining	8			
Note	rx 6073641- MB / br 1			
6/21/2024	8 ML	20242106@12	8/5/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.025% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $90.00	Last modified: 6/21/2024	by: BRENDA	
Remaining	8			
Note	rx 6049247- AM / br 1			
6/28/2024	15 ML	20242806@8	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.05% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $202.50	Last modified: 6/28/2024	by: BRENDA	
Remaining	15			
Note	rx 6055832+ stock- AM /br 1			
7/2/2024	10 ML	20240207@29	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.05% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $135.00	Last modified: 7/2/2024	by: BRENDA	
Remaining	10			
Note	rx 6069102- am /br 1			
7/8/2024	25 ML	20240807@97	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.05% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $337.50	Last modified: 7/9/2024	by: BRENDA	
Remaining	25			
Note	stock- MB / br 1			

[redacted]

Date made	Qty made& units	Lot number	Beyond use date	Active
7/10/2024	8 ML	20241007@25	8/24/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.1% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $122.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	8			
Note RX 6054763- MB / BR 1				
7/15/2024	8 ML	20241507@12	8/29/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.1% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $122.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	8			
Note rx 6071289- MB / br 1				
6/25/2024	8 ML	20242506@15	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.125% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $122.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	8			
Note rx 6058813- MB / br 1				
6/19/2024	8 ML	20241906@18	8/3/2024	Finalized: ☐ Temp Log: ☐ ☑
ATROPINE SULFATE 0.15% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $122.00	Last modified: 6/19/2024	by: BRENDA	
Remaining	8			
Note New Log Originally made as: 8 ATROPINE SULFATE 0.15% OPHTHALMIC Formula ID: 16040				
6/17/2024	50 ML	20241706@67	12/14/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $296.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
7/10/2024	50 ML	20241007@91	1/6/2025	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $296.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
6/27/2024	100 ML	20242706@83	12/24/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 6/28/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				

Log report (detailed)

Printed: 7/15/2024 2:54 PM

Report Dates between 6/1/2024 and 7/31/2024

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	50 ML	20242406@58	10/1/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $296.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
7/5/2024	100 ML	20240507@44	1/1/2025	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
7/2/2024	100 ML	20240207@103	12/29/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
7/12/2024	50 ML	20241207@60	1/8/2025	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 20% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $296.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 20% OPHTHALMIC Formula ID: 4784				
6/28/2024	100 ML	20242806@32	12/25/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 25% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 6/28/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 25% OPHTHALMIC Formula ID: 8077				
7/1/2024	100 ML	20240107@116	12/28/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 25% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 7/1/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 25% OPHTHALMIC Formula ID: 8077				
7/9/2024	100 ML	20240907@106	1/5/2025	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 25% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $500.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 25% OPHTHALMIC Formula ID: 8077				

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/17/2024	100 ML	20241706@57	12/14/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 30% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $500.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 30% OPHTHALMIC Formula ID: 11361				
6/26/2024	100 ML	20242606@46	12/23/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 30% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 6/26/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 30% OPHTHALMIC Formula ID: 11361				
6/20/2024	100 ML	20242006@73	12/17/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 50% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $500.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/19/2024	50 ML	20241906@65	12/16/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 50% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	MAYO	AMAYA		
Cost $0.00	AWP $280.00	Last modified: 6/19/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/20/2024	50 ML	20242006@46	12/17/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 50% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $280.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/20/2024	50 ML	20242006@49	12/17/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 50% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $280.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/17/2024	50 ML	20241706@63	12/14/2024	Finalized: ☐ Temp Log: ☐ ☑
AUTOLOGOUS SERUM 50% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $280.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	50 ML	20242406@64	12/21/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $280.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/24/2024	50 ML	20242406@68	12/21/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $280.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	50			
Note New Log Originally made as: 50 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
6/26/2024	40 ML	20242606@42	12/23/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $240.00	Last modified: 6/26/2024	by: BRENDA	
Remaining	40			
Note New Log Originally made as: 40 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
7/11/2024	100 ML	20241107@88	1/7/2025	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $500.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
7/16/2024	100 ML	20241607@129	1/12/2025	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $500.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
7/17/2024	100 ML	20241707@53	1/13/2025	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐
AUTOLOGOUS SERUM 50% OPHTHALMIC				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $500.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	100			
Note New Log Originally made as: 100 AUTOLOGOUS SERUM 50% OPHTHALMIC Formula ID: 4880				
7/3/2024	25 SYR	20240307@20	10/1/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑
AVASTIN 25 MG/ML 0.05 ML PFS INJECTABLE				
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $250.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	25			
Note stock-__MB__/br1____				

Date made	Qty made & units	Lot number	Beyond use date	Active
7/3/2024	25 SYR	20240307@22	10/1/2024	Finalized: ☐ Temp Log: ☐ ☑
AVASTIN 25 MG/ML 0.05 ML PFS INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $250.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	25			
Note	stock- _MB___/br1___			
7/3/2024	35 SYR	20240307@24	10/1/2024	Finalized: ☐ Temp Log: ☐ ☑
AVASTIN 25 MG/ML 0.05 ML PFS INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $350.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	35			
Note	stock- am/ br2			
7/3/2024	25 SYR	20240307@18	10/1/2024	Finalized: ☐ Temp Log: ☐ ☑
AVASTIN 25 MG/ML 0.05 ML PFS INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $250.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	25			
Note	stock- am/br2			
7/15/2024	10 ML	20241507@55	1/11/2025	Finalized: ☐ Temp Log: ☐ ☑
BENZALKONIUM CHLORIDE 5% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	7.54			
Note	stock- mb/br1			
7/2/2024	10 ML	20240207@44	9/30/2024	Finalized: ☐ Temp Log: ☐ ☑
BENZALKONIUM CHLORIDE (W/V) 0.1% INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	-18.4			
Note	STOCK/GLINT-___mb_/ PREP			
6/26/2024	50 ML	20242606@4	8/10/2024	Finalized: ☐ Temp Log: ☐ ☑
BETADINE 5% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/26/2024	by: BRENDA	
Remaining	50			
Note	wang- _MB__/ br 1___			
6/19/2024	10 GM	20241906@16	7/17/2024	Finalized: ☐ Temp Log: ☐ ☑
BRINZOLAMIDE+TIMOLOL OPHTH 2%+0.5% OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	10			
Note	RX 6057761- mb/AM/BR 2___/ OVEN			

Date made	Qty made & units	Lot number	Beyond use date	Active
6/20/2024	15 GM	20242006@30	7/18/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.09% OINTMENT

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $375.00 Last modified: 6/20/2024 by: BRENDA
Remaining 15

Note rx 6073180+6066644- cmk

7/11/2024	20 GM	20241107@78	8/8/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.09% OINTMENT

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $500.00 Last modified: 7/11/2024 by: BRENDA
Remaining 20

Note 3 rx- cmk

6/18/2024	45 GMS	20241806@20	7/16/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.1% OINTMENT

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,125.00 Last modified: 6/19/2024 by: BRENDA
Remaining 25

Note 2 rx- mb/KC/BR 1___/ oven

7/1/2024	50 GMS	20240107@6	7/29/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.1% OINTMENT

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,250.00 Last modified: 7/2/2024 by: BRENDA
Remaining 45

Note stock+ rx- _mb/am/br2__/ oven

7/1/2024	5 GMS	20240107@23	7/29/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.1% OINTMENT

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $125.00 Last modified: 7/1/2024 by: BRENDA
Remaining 5

Note rx 6074038- cmk

7/10/2024	50 GMS	20241007@29	8/7/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.1% OINTMENT

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,250.00 Last modified: 7/11/2024 by: BRENDA
Remaining 30

Note STOCK+ MULTIPLE RX- _mb__/ OVEN

7/9/2024	5 GMS	20240907@49	8/6/2024	Finalized: ☐ Temp Log: ☐ NIOSH ☐ ☑

BROMFENAC OPHTH 0.1% OINTMENT

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $125.00 Last modified: 7/9/2024 by: BRENDA
Remaining 5

Note rx 6051315- cmk

Date made	Qty made & units	Lot number	Beyond use date	Active
7/16/2024	50 GMS	20241607@74	8/13/2024	Finalized: ☐ Temp Log: ☐ ☑
BROMFENAC OPHTH 0.1% OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $1,250.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	50			
Note	replacement+ stock- mb/oven-BR 2			
6/27/2024	7 ML	20242706@6	7/1/2024	Finalized: ☐ Temp Log: ☐ ☑
BROMFENAC OPHTH (PF) 0.07% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $155.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	7			
Note	rx 6073196- _mb__/ br 1____			
7/2/2024	40 ML	20240207@10	12/29/2024	Finalized: ☐ Temp Log: ☐ ☑
BROMFENAC+PVP 0.05%+0.5% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	40			
Note	rx 6073777- _mb__/ br_1__/autoclave			
7/10/2024	450 ML	20241007@92	11/7/2024	Finalized: ☐ Temp Log: ☐ ☑
BSS (REPACK COMM) INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	35.9			
Note	New Log Originally made as: 450 BSS (REPACK COMM) INJECTABLE Formula ID: 17563			
6/17/2024	360 ML	20241706@78	10/15/2024	Finalized: ☐ Temp Log: ☐ ☑
BSS (REPACK COMM) INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $0.00	Last modified: 6/19/2024	by: BRENDA	
Remaining	-35			
Note	STOCK KC BR6			
7/5/2024	928.8 ML	20240507@1	7/15/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $2,180.28	Last modified: 7/11/2024	by: BRENDA	
Remaining	928.8			
Note	muve- _AM/MB/BR 1/BR 2			
6/21/2024	774 ML	20242106@11	7/1/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $1,816.90	Last modified: 6/21/2024	by: BRENDA	
Remaining	774			
Note	muve- __MB_/ br 1____			

Log report (detailed)

Date made	Qty made& units	Lot number	Beyond use date	Active
6/19/2024	258 ML	20241906@6	6/29/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $605.63 Last modified: 6/19/2024 by: BRENDA
Remaining 258
Note muve- KC BR1

6/28/2024 412.8 ML 20242806@9 7/8/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $969.01 Last modified: 6/28/2024 by: BRENDA
Remaining 412.8
Note muve- AM / br 1

6/26/2024 516 ML 20242606@25 7/6/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,211.27 Last modified: 6/27/2024 by: BRENDA
Remaining 516
Note muve- AM / br 2

7/11/2024 516 ML 20241107@14 7/21/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,211.27 Last modified: 7/15/2024 by: BRENDA
Remaining 516
Note muve- rc / br 2

7/9/2024 670.8 ML 20240907@14 7/19/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,574.65 Last modified: 7/9/2024 by: BRENDA
Remaining 670.8
Note muve- rc/ br 2

7/16/2024 258 ML 20241607@7 7/26/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $605.63 Last modified: 7/16/2024 by: BRENDA
Remaining 258
Note muve- RAJ / br 2

7/15/2024 51.6 ML 20241507@39 7/25/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

BUPIVA+EPI+KETOROLAC+MORPH 0.25%+1:200,000+30MG+6MG INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $121.13 Last modified: 7/15/2024 by: BRENDA
Remaining 51.6
Note muve- MB / BR 1

Date made	Qty made& units	Lot number	Beyond use date	Active
6/26/2024	50.6 ML	20242606@26	7/6/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVA+EPI+MORPH 0.25%+1:200,000+6MG INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $118.78	Last modified: 6/26/2024	by: BRENDA	
Remaining	50.6			
Note	rx 20004876- MB/ br 1			
6/20/2024	30 ML	20242006@15	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVACAINE HCL (MPF) 0.75% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $210.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	30			
Note	cataract- MB / br 1			
6/20/2024	8 ML	20242006@26	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVACAINE HCL (MPF) 0.75% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $56.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	8			
Note	cataract- cmk			
7/11/2024	70 ML	20241107@2	7/15/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPIVACAINE+EPI+DEH ALC(INJ) 0.5%+0.0005%+4% INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $126.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	70			
Note	rx 6074753- MB /br 1			
6/24/2024	60 ML	20242406@32	7/22/2024	Finalized: ☐ Temp Log: ☐ ☑
BUPRENORPHINE (MDV) 0.3 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $320.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	60			
Note	faithful friends- cmk			
6/25/2024	20 ML	20242506@62	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
CEFAZOLIN OPHTH (PF) IN BSS 50 MG/ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $110.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	20			
Note	rx 6073619- AM / br 1			
6/17/2024	5 ML	20241706@17	8/1/2024	Finalized: ☐ Temp Log: ☐ ☑
CIDOFOVIR (PF) 40 MG/ML INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $95.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	5			
Note	rx 6072206-kc /br1/ autoclave			

Date made	Qty made & units	Lot number	Beyond use date	Active
7/15/2024	10 ML	20241507@1	8/29/2024	Finalized: ☐ Temp Log: ☐ ☑
CIDOFOVIR (PF) 45MG/3ML INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $190.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	10			
Note	rx 6075058+6073454- am / autoclave			
6/20/2024	5 ML	20242006@18	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑
CIDOFOVIR (PF) 56.25MG/3ML INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $95.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	5			
Note	rx 6073156- AM/KC/BR 1 / autoclave			
6/24/2024	5 ML	20242406@80	8/8/2024	Finalized: ☐ Temp Log: ☐ ☑
CIDOFOVIR (PF) 56.25MG/3ML INJECTABLE				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $95.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	5			
Note	RX 6073487- AM/AUTOCLAVE/BR2			
6/19/2024	20 ML	20241906@76	8/3/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOPENTO+PHENYLEPH+TROPIC 1%+2.5%+1% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $400.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	20			
Note	docs+ stock- mb/ br 1			
7/11/2024	20 ML	20241107@7	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOPENTO+PHENYLEPH+TROPIC 1%+2.5%+1% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $400.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	20			
Note	stock- AM / br 5			
6/26/2024	12 ML	20242606@22	7/24/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOSPORINE (MCT OIL) SOLUTION 1% OPHTHALMIC				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $78.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	12			
Note	rx 6056338- am/ mb/br 1 / oven			
7/2/2024	12 ML	20240207@16	7/30/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOSPORINE (MCT OIL) SOLUTION 1% OPHTHALMIC				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $78.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	12			
Note	rx 6074311- MB / oven			

Date made	Qty made & units	Lot number	Beyond use date	Active
7/1/2024	450 ML	20240107@1	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE AQ EMULSION 1% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,925.00 Last modified: 7/11/2024 by: BRENDA
Remaining 450

Note **stock- __mb/br 1_ / autoclave**

7/15/2024 450 ML 20241507@3 9/13/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE AQ EMULSION 1% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,925.00 Last modified: 7/15/2024 by: BRENDA
Remaining 450

Note **stock- __am__/ autoclave**

7/10/2024 12 ML 20241007@7 8/7/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE AQUEOUS EMULSION 0.2% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $78.00 Last modified: 7/11/2024 by: BRENDA
Remaining 12

Note **rx 6074532- AM/MB / autoclave / BR 1**

6/27/2024 12 ML 20242706@5 7/25/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE AQUEOUS EMULSION 2% OPHTHALMIC

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $114.00 Last modified: 6/28/2024 by: BRENDA
Remaining 12

Note **rx 6071388- _MB/BR 2__/ autoclave**

7/16/2024 12 ML 20241607@12 8/13/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE AQUEOUS EMULSION 2% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $114.00 Last modified: 7/17/2024 by: BRENDA
Remaining 12

Note **rx 6058271- _am/mb / autoclave/ br 2**

6/24/2024 10 GM 20242406@11 12/21/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE OINTMENT 1% OPHTHALMIC

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $150.00 Last modified: 6/25/2024 by: BRENDA
Remaining 10

Note **rx 6073306- MB/BR 1___/oven**

7/10/2024 10 GM 20241007@8 8/7/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE OINTMENT 2% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $150.00 Last modified: 7/12/2024 by: BRENDA
Remaining 10

Note **rx 6074729- _MB/ BR 1__/ oven**

Date made	Qty made & units	Lot number	Beyond use date	Active
7/2/2024	10 ML	20240207@27	7/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 0.2% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $60.00 Last modified: 7/2/2024 by: BRENDA
Remaining 10

Note rx 6052643- am /br1

6/26/2024 10 ML 20242606@23 7/24/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 0.5% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $65.00 Last modified: 6/26/2024 by: BRENDA
Remaining 10

Note rx 6068961- MB / br 1

7/8/2024 10 ML 20240807@12 8/5/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 0.5% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $65.00 Last modified: 7/8/2024 by: BRENDA
Remaining 10

Note rx 6074436- MB / br 1

7/1/2024 155 ML 20240107@4 8/30/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 1% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $620.00 Last modified: 7/2/2024 by: BRENDA
Remaining 155

Note stock- AM/BR 1 / oven

7/16/2024 200 ML 20241607@3 9/14/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 1% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $800.00 Last modified: 7/16/2024 by: BRENDA
Remaining 200

Note stock- am/oven

7/17/2024 90 ML 20241707@24 8/31/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE SOLUTION 2% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $450.00 Last modified: 7/17/2024 by: BRENDA
Remaining 90

Note stock+ 2 rx-ambr5/oven

6/19/2024 12 ML 20241906@11 7/3/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

CYCLOSPORINE+TACROLIMUS 2%+0.02% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $114.00 Last modified: 6/20/2024 by: BRENDA
Remaining 12

Note rx 6073031- MB/BR 1 / oven

Log report (detailed)

Date made	Qty made& units	Lot number	Beyond use date	Active
6/20/2024	12 ML	20242006@14	7/4/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOSPORINE+TACROLIMUS 2%+0.03% OPHTHALMIC				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $114.00	Last modified: 6/21/2024	by: BRENDA	
Remaining	12			
Note	rx 6051720- AM/MB/BR 2_/ oven			
6/24/2024	12 ML	20242406@21	7/22/2024	Finalized: ☐ Temp Log: ☐ ☑
CYCLOSPORINE+TACROLIMUS AQ EMULSION 2%+0.03% OPHTHALMIC				NIOSH ☑
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $144.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	12			
Note	rx 6059111- AM/autoclave MB/BR1			
7/8/2024	5 ML	20240807@10	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
DESMOPRESSIN ACETATE 100 MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $90.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	5			
Note	rx 6068682- _MB__/ br1____			
6/17/2024	25 ML	20241706@53	8/1/2024	Finalized: ☐ Temp Log: ☐ ☑
DESMOPRESSIN ACETATE (PLASTIC DROP) 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $450.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	25			
Note	stock+ rx 6072875- _AM__/ br 1____			
6/24/2024	13 ML	20242406@85	8/8/2024	Finalized: ☐ Temp Log: ☐ ☑
DESMOPRESSIN ACETATE (PLASTIC DROP) 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $234.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	13			
Note	rx 6073424- cmk			
7/8/2024	20 ML	20240807@11	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
DESMOPRESSIN ACETATE (PLASTIC DROP) 0.01% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $360.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	20			
Note	rx 6065993+ stock- MB/ br 1			
6/17/2024	25 ML	20241706@47	6/17/2025	Finalized: ☐ Temp Log: ☐ ☑
DESMOPRESSIN ACETATE CMPD STOCK 100 MCG/ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $675.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	-25			
Note	stock- AM__/ br 1___			

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date		Active
7/8/2024	25 ML	20240807@9	7/8/2025	Finalized: ☐ Temp Log: ☐	☑
DESMOPRESSIN ACETATE CMPD STOCK 100 MCG/ML SOLUTION				NIOSH	☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $675.00	Last modified: 7/8/2024	by: BRENDA		
Remaining	0				
Note	stock+ 2 rx(1 inj/1 opth-see separate formulas)- MB / br 1				
7/3/2024	12 ML	20240307@10	8/17/2024	Finalized: ☐ Temp Log: ☐	☑
DEXAMETHASONE (PF) OPHTH 0.1% SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $78.00	Last modified: 7/3/2024	by: BRENDA		
Remaining	12				
Note	rx 6074353- AM / br 5				
6/24/2024	10 GMS	20242406@13	6/28/2024	Finalized: ☐ Temp Log: ☐	☑
DEXAMETHASONE OPHTH (PF) 0.1% OINTMENT				NIOSH	☑
KOMM, PHAR CAITLIN	COLE	KAT			
Cost $0.00	AWP $130.00	Last modified: 6/24/2024	by: BRENDA		
Remaining	10				
Note	rx 6072925- AM/ br5				
7/11/2024	15 ML	20241107@11	8/25/2024	Finalized: ☐ Temp Log: ☐	☑
DEXAMETHASONE OTIC (PF) 24 MG/ML INJECTABLE				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $450.00	Last modified: 7/15/2024	by: BRENDA		
Remaining	13.16				
Note	stock- am/br5				
7/11/2024	5 ML	20241107@12	8/25/2024	Finalized: ☐ Temp Log: ☐	☑
DEXAMETHASONE SOD PHOS (PF) 10 MG/ML INJECTABLE				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $81.67	Last modified: 7/11/2024	by: BRENDA		
Remaining	5				
Note	rx 6060817-am/br5				
6/18/2024	10 GMS	20241806@18	7/16/2024	Finalized: ☐ Temp Log: ☐	☑
DICLOFENAC OPHTH 0.1% OINTMENT				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $93.33	Last modified: 6/19/2024	by: BRENDA		
Remaining	10				
Note	rx 6072948- KC/BR 1 /oven				
7/10/2024	10 GMS	20241007@24	8/7/2024	Finalized: ☐ Temp Log: ☐	☑
DICLOFENAC OPHTH 0.1% OINTMENT				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $93.33	Last modified: 7/11/2024	by: BRENDA		
Remaining	10				
Note	RX 6066413- MB / OVEN / BR 1				

Date made	Qty made & units	Lot number	Beyond use date	Active
7/15/2024	10 GMS	20241507@5	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
DICLOFENAC OPHTH 0.1% OINTMENT				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $93.33 Last modified: 7/16/2024 by: BRENDA
Remaining 10

Note rx 6075039- mb/br 2/ oven

7/11/2024 160 ML 20241107@1 8/8/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE CALCIUM DISODIUM (PF) 200 MG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/11/2024 by: BRENDA
Remaining 160

Note 15 rx- AM/BR 2 / autoclave

6/27/2024 160 ML 20242706@4 7/25/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE CALCIUM DISODIUM (PF) 200 MG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/27/2024 by: BRENDA
Remaining 160

Note 15rx- mb / autoclave

6/25/2024 12 ML 20242506@16 7/23/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE CALCIUM DISODIUM (PF) 200 MG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/25/2024 by: BRENDA
Remaining 12

Note rx 6067645- MB/autoclave

6/26/2024 12 ML 20242606@24 7/24/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE CALCIUM DISODIUM (PF) 60 MG/ML INJECTABLE NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/26/2024 by: BRENDA
Remaining 12

Note rx 6067645- MB/BR 1 / autoclave

6/17/2024 22 ML 20241706@25 7/15/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE DISODIUM OPHTH (PF) (EDTA) 2% SOLUTION NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $110.00 Last modified: 6/18/2024 by: BRENDA
Remaining 22

Note rx 6072735- KC/BR 1 / autoclave

7/1/2024 23 ML 20240107@12 7/29/2024 Finalized: ☐ Temp Log: ☐ ☑
EDETATE DISODIUM OPHTH (PF) (EDTA) 2% SOLUTION NIOSH ☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $115.00 Last modified: 7/3/2024 by: BRENDA
Remaining 23

Note rx 6073878- MB/ autoclave/ BR 1

SaveWay Compounding Pharmacy INC
31 Albe Drive Unit 1
877-285-8143
Newark, DE 19702 Ph: 302-369-5520

Date made	Qty made& units	Lot number	Beyond use date	Active
6/20/2024	12 ML	20242006@23	7/18/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 0.1 MOLAR (3.75%) OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	12			
Note	rx 6072996- _AM/BR 2__/ autoclave			
6/21/2024	12 ML	20242106@14	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 1.5% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $90.00	Last modified: 6/21/2024	by: BRENDA	
Remaining	12			
Note	2 rx+ stock- MB/_BR 1__/ autoclave			
7/15/2024	25 ML	20241507@9	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 2.5% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	25			
Note	rx 6075970- _AM__/autoclave			
6/27/2024	23 ML	20242706@9	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 2.5% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	23			
Note	rx 6073610- _mb/br 1__/autoclave			
6/25/2024	60 ML	20242506@18	7/23/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 3% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $450.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	60			
Note	stock- MB/ autoclave _AM/BR2			
7/9/2024	22 ML	20240907@6	8/6/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA (PF) 3% OPHTHALMIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $165.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	22			
Note	stock- mb / autoclave / br 1			
6/17/2024	10 GM	20241706@21	7/15/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA OPHTHALMIC 2% OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $120.00	Last modified: 6/17/2024	by: BRENDA	
Remaining	10			
Note	rx 6072727- _AM_/ oven			



Date made	Qty made& units	Lot number	Beyond use date	Active
6/19/2024	15 GM	20241906@10	7/17/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA OPHTHALMIC 3 % OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $225.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	15			
Note	rx 6073099+ stock- mb/BR 1___ / oven			
7/9/2024	10 GM	20240907@30	8/6/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA OPHTHALMIC 3 % OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $150.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	10			
Note	rx 6073099- MB / oven/ BR 1			
7/17/2024	10 GM	20241707@31	8/14/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA OPHTHALMIC 3 % OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $150.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	10			
Note	rx-_____-___/ br___			
7/17/2024	10 GM	20241707@17	8/14/2024	Finalized: ☐ Temp Log: ☐ ☑
EDTA OPHTHALMIC 3 % OINTMENT				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $150.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	10			
Note	rx-_____-___/ oven			
7/17/2024	500 GMS	20241707@21	8/31/2024	Finalized: ☐ Temp Log: ☐ ☑
ENRO+KETO+TRIAM OINT 1%+2%+0.1% OTIC				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $1,666.67	Last modified: 7/17/2024	by: BRENDA	
Remaining	500			
Note	stock+ rx-_AM__/ prep			
7/17/2024	22 ML	20241707@19	8/21/2024	Finalized: ☐ Temp Log: ☐ ☑
ENRO+MICON+DEX (POLOX) 2%+0.5%+0.1% OTIC				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	22			
Note	rx 6075411-_AM__/ prep			
6/18/2024	7 EA	20241806@58	6/28/2024	Finalized: ☐ Temp Log: ☐ ☑
EPI+LIDO IN BSS(EPI-SHUGARCAINE) 0.025%+0.75% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $140.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	7			
Note	tri county-_KC__/ br 1___			

Date made	Qty made& units	Lot number	Beyond use date	Active
7/3/2024	5 EA	20240307@4	7/13/2024	Finalized: ☐ Temp Log: ☐ ☑
EPI+LIDO IN BSS(EPI-SHUGARCAINE) 0.025%+0.75% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $100.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	5			
Note 5 rx- _AM__/ br 2				
7/5/2024	5 EA	20240507@3	7/15/2024	Finalized: ☐ Temp Log: ☐ ☑
EPI+LIDO IN BSS(EPI-SHUGARCAINE) 0.025%+0.75% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $100.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	5			
Note tri-county- ___AM_/ br 1				
7/16/2024	6 EA	20241607@14	7/26/2024	Finalized: ☐ Temp Log: ☐ ☑
EPI+LIDO IN BSS(EPI-SHUGARCAINE) 0.025%+0.75% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $120.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	6			
Note tri-county- am/ br 2				
6/18/2024	100 ML	20241806@126	6/19/2024	Finalized: ☐ Temp Log: ☐ ☑
ERTAPENEM 1 GM/100ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $25.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	100			
Note rx 6073150- mb br1				
7/5/2024	200 ML	20240507@69	7/6/2024	Finalized: ☐ Temp Log: ☐ ☑
ERTAPENEM 1 GM/100ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $25.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	200			
Note hospice- _am__/ br 1				
7/8/2024	20 ML	20240807@98	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
ETHANOL 98% INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $180.00	Last modified: 7/9/2024	by: BRENDA	
Remaining	20			
Note STOCK+ RX- MB/ BR 1				
7/15/2024	5 ML	20241507@4	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑
FLUOROURACIL OPHTH 1% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $75.00	Last modified: 7/15/2024	by: BRENDA	
Remaining	5			
Note rx 6075042- _MB__/ br 1				

Log report (detailed)

Date made	Qty made& units	Lot number	Beyond use date	Active
6/25/2024	10 ML	20242506@63	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GENTAMICIN OPHTH (FROM INJ) 0.3% SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/25/2024 by: BRENDA
Remaining 10

Note rx 6073620- am/br2

6/21/2024 325 ML 20242106@18 7/21/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GENTAMICIN SULF IN NS (PF) 0.48 MG/ML IRRIGATION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $65.00 Last modified: 6/21/2024 by: BRENDA
Remaining 325

Note RX 6065982- MB / BR 2

7/1/2024 1000 ML 20240107@9 7/31/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GENTAMICIN SULF IN NS (PF) 0.48 MG/ML IRRIGATION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $95.00 Last modified: 7/1/2024 by: BRENDA
Remaining 1000

Note rx 6072410- RAJ / br 2

7/1/2024 100 ML 20240107@2 8/15/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GLUTATHIONE INHALATION (PF) 200 MG/ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $130.83 Last modified: 7/1/2024 by: BRENDA
Remaining 100

Note rx 6071812- mb/ rc / br 1

6/17/2024 7 ML 20241706@15 6/27/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GLYCERIN 30% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/17/2024 by: BRENDA
Remaining 7

Note rx 6072777- AM / br 1

7/5/2024 65 ML 20240507@2 8/2/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GLYCERIN 40 % SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/5/2024 by: BRENDA
Remaining 65

Note rx 6074479+ stock- am / autoclave

7/3/2024 65 ML 20240307@80 7/31/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

GLYCERIN 40 % SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/5/2024 by: BRENDA
Remaining 65

Note RX 6074410- AM/ AUTOCLAVE

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/17/2024	10 ML	20241706@55	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HUMAN CHORIONIC GONADOTROPIN (CRN) 1,000 U/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $190.00 Last modified: 6/17/2024 by: BRENDA
Remaining 10

Note rx 6065928- ___ / br

6/17/2024	10 ML	20241706@58	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HUMAN CHORIONIC GONADOTROPIN (P) 1,000 U/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/17/2024 by: BRENDA
Remaining 10

Note rx 6065928- KC / br 1

7/3/2024	45 ML	20240307@29	8/17/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROGEN PEROXIDE INHALATION 3% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/3/2024 by: BRENDA
Remaining 45

Note rx 6068714- MB / br1

6/21/2024	500 ML	20242106@19	7/1/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROMORPHONE HCL IV (PF) 1 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $950.00 Last modified: 6/21/2024 by: BRENDA
Remaining 500

Note STOCK- AM / BR 1

7/9/2024	500 ML	20240907@50	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROMORPHONE HCL IV (PF) 1 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $950.00 Last modified: 7/11/2024 by: BRENDA
Remaining 500

Note stock+ hospice- cmk

7/9/2024	500 ML	20240907@98	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROMORPHONE HCL IV (PF) 1 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $950.00 Last modified: 7/9/2024 by: BRENDA
Remaining 500

Note STOCK- MB / BR 1

7/15/2024	500 ML	20241507@15	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROMORPHONE HCL IV (PF) 1 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $950.00 Last modified: 7/15/2024 by: BRENDA
Remaining 500

Note stock- rc/br2

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	35 ML	20242406@4	8/8/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXOCOBALAMIN INJ 25 MG/ML SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/24/2024 by: BRENDA
Remaining 35

Note rx 6052656- MB / br 1

7/1/2024 35 ML 20240107@7 8/15/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXOCOBALAMIN INJ 25 MG/ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/1/2024 by: BRENDA
Remaining 35

Note rx 6052741- mb/ / br 1

7/17/2024 35 ML 20241707@11 8/31/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXOCOBALAMIN INJ 25 MG/ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/17/2024 by: BRENDA
Remaining 35

Note rx 6073771- MB/ / br

7/9/2024 10 ML 20240907@35 8/23/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXOCOBALAMIN INJ (PF) 1000 MCG/ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $72.00 Last modified: 7/9/2024 by: BRENDA
Remaining 10

Note rx 6065397- MB/ br 1

6/18/2024 10 GM 20241806@38 12/15/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXYETHYLCELLULOSE 4% GEL

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/19/2024 by: BRENDA
Remaining 10

Note stock- MB / autoclave

7/15/2024 10 GM 20241507@10 1/11/2025 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

HYDROXYETHYLCELLULOSE 4% GEL

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/15/2024 by: BRENDA
Remaining 4

Note stock/for rx- am /autoclave

7/15/2024 10 ML 20241507@2 7/19/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

IODINE + DMSO OPHTH 0.25% + 6.25% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $90.00 Last modified: 7/15/2024 by: BRENDA
Remaining 10

Note rx 6074944- AM / br 1

Date made	Qty made & units	Lot number	Beyond use date	Active
7/16/2024	4875 ML	20241607@134	10/14/2024	Finalized: ☐ Temp Log: ☐ ☑
ISOPROPYL ALCOHOL (0.2 UM FILTERED) 70% SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	4875			
Note	**stock MB/BR2**			
6/20/2024	15 ML	20242006@16	6/30/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $225.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	15			
Note	**cataract- MB / br 1**			
6/21/2024	5 ML	20242106@43	7/1/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $75.00	Last modified: 6/21/2024	by: BRENDA	
Remaining	5			
Note	**CATARACT (5RX)- / BR**			
6/25/2024	15 ML	20242506@19	7/5/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $225.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	15			
Note	**cataract+ stock- MB/BR1**			
7/1/2024	6 ML	20240107@115	7/11/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $90.00	Last modified: 7/1/2024	by: BRENDA	
Remaining	6			
Note	**cataract- cmk**			
7/10/2024	10 ML	20241007@5	7/20/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $150.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	10			
Note	**stock- MB / br 1**			
7/2/2024	10 ML	20240207@31	7/12/2024	Finalized: ☐ Temp Log: ☐ ☑
KENALOG 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $150.00	Last modified: 7/2/2024	by: BRENDA	
Remaining	10			
Note	**rx cataract- raj /br 2**			

Date made	Qty made& units	Lot number	Beyond use date	Active
7/16/2024	10 ML	20241607@9	7/26/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KENALOG 10 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $150.00 Last modified: 7/16/2024 by: BRENDA
Remaining 10

Note stock+ cataract- raj/ br 2

7/17/2024 60 ML 20241707@1 8/21/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KETAMINE NASAL SPRAY 10% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $162.50 Last modified: 7/17/2024 by: BRENDA
Remaining 60

Note rx 40004683- am / br 1

6/27/2024 60 ML 20242706@2 8/1/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KETAMINE NASAL SPRAY 10% SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $162.50 Last modified: 6/27/2024 by: BRENDA
Remaining 60

Note rx 40004596- am/mb / br 1

7/5/2024 30 ML 20240507@6 8/9/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KETAMINE NASAL SPRAY 10% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $90.00 Last modified: 7/5/2024 by: BRENDA
Remaining 30

Note rx 40003791- AM / br 1

7/9/2024 30 ML 20240907@59 8/13/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KETAMINE NASAL SPRAY 10% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $90.00 Last modified: 7/11/2024 by: BRENDA
Remaining 30

Note rx 40004570- MB/BR 1

6/18/2024 30 ML 20241806@59 7/23/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

KETAMINE NASAL SPRAY 12% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $110.00 Last modified: 6/18/2024 by: BRENDA
Remaining 30

Note rx 40004524- mb/ / br 2

6/18/2024 11 SYR 20241806@14 6/28/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

LIDO+BUPIV+DEXA+NAHCO3+HEPARIN 0.435%+0.109%+0.0218%+0.914%+10,000 UN INJ

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $22.72 Last modified: 6/18/2024 by: BRENDA
Remaining 11

Note stock- AM/KC / br 1

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	8 SYR	20242406@74	7/4/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDO+BUPIV+DEXA+NAHCO3+HEPARIN 0.435%+0.109%+0.0218%+0.914%+10,000 UN INJ				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $16.52	Last modified: 6/24/2024	by: BRENDA	
Remaining	8			
Note jefferson- MB / br 1				
7/9/2024	7 SYR	20240907@11	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDO+BUPIV+DEXA+NAHCO3+HEPARIN 0.435%+0.109%+0.0218%+0.914%+10,000 UN INJ				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $14.46	Last modified: 7/9/2024	by: BRENDA	
Remaining	7			
Note jefferson- RC / br 2				
7/16/2024	4 SYR	20241607@8	7/26/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDO+BUPIV+DEXA+NAHCO3+HEPARIN 0.435%+0.109%+0.0218%+0.914%+10,000 UN INJ				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $8.26	Last modified: 7/16/2024	by: BRENDA	
Remaining	4			
Note jefferson- raj/ br 2				
6/24/2024	50 ML	20242406@19	7/4/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDOCAINE + EPI (D) (MDV) 1% + 1:100,000 INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $300.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	50			
Note rx 6043429- MB / br 1				
7/8/2024	50 ML	20240807@2	7/18/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDOCAINE + EPI (D) (MDV) 1% + 1:100,000 INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $300.00	Last modified: 7/8/2024	by: BRENDA	
Remaining	50			
Note rx 6074280- MB / br 1 -				
7/5/2024	32 ML	20240507@4	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDOCAINE HCL NASAL 4% SPRAY				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $48.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	32			
Note rx 6074486- AM / prep				
7/12/2024	25 ML	20241207@31	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑
LIDOCAINE HCL+TETRACAINE HCL TOPICAL 4%+4% GEL				NIOSH ☐
SHENYO, RP AMY D.	HORNOR	JILL		
Cost $0.00	AWP $0.00	Last modified: 7/12/2024	by: JILL	
Remaining	0			
Note New Log Originally made as: 25 LIDOCAINE HCL+TETRACAINE HCL TOPICAL 4%+4% GEL Formula ID: 17880				

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date		Active
6/17/2024	12 ML	20241706@27	8/1/2024	Finalized: ☐ Temp Log: ☐	☑
LOSARTAN POTASSIUM OPHTH 0.8 MG/ML SOLUTION				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $0.00	Last modified: 6/17/2024	by: BRENDA		
Remaining	12				
Note	rx 6064625- AM /br 1				
6/18/2024	6000 ML	20241806@56	7/16/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $57.00	Last modified: 6/18/2024	by: BRENDA		
Remaining	6000				
Note	stock+ rx- AM / autoclave/mb/br1				
7/1/2024	6000 ML	20240107@8	7/29/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $570.00	Last modified: 7/2/2024	by: BRENDA		
Remaining	6000				
Note	stock- MB/RC/BR2 / autoclave				
6/26/2024	15 ML	20242606@27	7/24/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $1.14	Last modified: 6/27/2024	by: BRENDA		
Remaining	15				
Note	testing- MB/BR 1 / autoclave				
7/12/2024	6000 ML	20241207@4	8/9/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $570.00	Last modified: 7/15/2024	by: BRENDA		
Remaining	6000				
Note	stock- cmk / autoclave				
7/10/2024	6000 ML	20241007@22	8/7/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $570.00	Last modified: 7/11/2024	by: BRENDA		
Remaining	6000				
Note	STOCK 2 RX- MB / AUTOCLAVE/BR1				
7/2/2024	6000 ML	20240207@33	7/30/2024	Finalized: ☐ Temp Log: ☐	☑
LYSINE HCL+ARGININE HCL (PF-SWFI) 25G+25G/1000 ML INJECTABLE				NIOSH ☐	
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $570.00	Last modified: 7/3/2024	by: BRENDA		
Remaining	6000				
Note	stock- MB/BR 1 / autoclave				

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
7/12/2024	14 ML	20241207@38	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑
MARBOFLOX+CLOTRIMAZOLE OTIC 1%+1% SUSPENSION				NIOSH ☐
SHENYO, RP AMY D.	SANDERS	NICOLE		
Cost $0.00	AWP $70.00	Last modified: 7/12/2024	by: NSANDERS	
Remaining	14			
Note New Log Originally made as: 14 MARBOFLOX+CLOTRIMAZOLE OTIC 1%+1% SUSPENSION Formula ID: 19392				
7/5/2024	100 ML	20240507@9	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑
MEDIA FILL TEST - HIGH RISK				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	100			
Note melanie- ____ / br ____				
7/5/2024	100 ML	20240507@16	7/19/2024	Finalized: ☐ Temp Log: ☐ ☑
MEDIA FILL TEST - HIGH RISK				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	100			
Note Amaya- br _1 ____				
7/11/2024	13 ML	20241107@25	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑
METHYLCOBALAMIN (MB-12) (MDV) 1,000 MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $101.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	13			
Note rx 6074992- _AM/BR2__ / autoclave				
7/9/2024	28 ML	20240907@32	8/23/2024	Finalized: ☐ Temp Log: ☐ ☑
METHYLCOBALAMIN (MB-12) (MDV) 1,000 MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $131.00	Last modified: 7/10/2024	by: BRENDA	
Remaining	28			
Note rx 6067863- MB / autoclave/ BR 1				
7/2/2024	7 ML	20240207@42	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑
METHYLCOBALAMIN (MB-12) (PF) 5000 MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $39.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	7			
Note RX 6073915- _AM__ / BR 1 ____				
6/19/2024	100 ML	20241906@4	9/17/2024	Finalized: ☐ Temp Log: ☐ ☑
METHYLCOBALAMIN (PF) 20 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	100			
Note multiple rx- mb/autoclave kc br1				

Date made	Qty made & units	Lot number	Beyond use date	Active
6/19/2024	100 ML	20241906@5	9/17/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLCOBALAMIN (PF) 20 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/27/2024 by: BRENDA
Remaining 94.75

Note stock+ rx- mb/am/autoclave/br1

7/10/2024 100 ML 20241007@21 10/8/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLCOBALAMIN (PF) 20 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/11/2024 by: BRENDA
Remaining 100

Note stock- MB / autoclave / BR 1

7/10/2024 100 ML 20241007@17 10/8/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLCOBALAMIN (PF) 20 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/10/2024 by: BRENDA
Remaining 100

Note stock- ___ / autoclave

7/10/2024 100 ML 20241007@18 10/8/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLCOBALAMIN (PF) 20 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/15/2024 by: BRENDA
Remaining 100

Note stock- mb/ autoclave/ br 1

6/18/2024 6 ML 20241806@74 6/28/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLENE BLUE (1%) (DIL) 10 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $64.67 Last modified: 6/18/2024 by: BRENDA
Remaining 6

Note docs-cmk

7/1/2024 10 ML 20240107@45 7/11/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLENE BLUE (1%) (DIL) 10 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $102.00 Last modified: 7/1/2024 by: BRENDA
Remaining 10

Note docs- rc/br2

7/8/2024 10 ML 20240807@7 7/18/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

METHYLENE BLUE (1%) (DIL) 10 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $102.00 Last modified: 7/8/2024 by: BRENDA
Remaining 10

Note docs- RC / br 2

Date made	Qty made & units	Lot number	Beyond use date		Active
7/8/2024	10 ML	20240807@63	7/18/2024	Finalized: ☐ Temp Log: ☐	☑
METHYLENE BLUE (1%) (DIL) 10 MG/ML INJECTABLE				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $102.00 Last modified: 7/8/2024 by: BRENDA
Remaining 10

Note **STOCK+ RX- rc / BR 2**

7/17/2024	10 ML	20241707@23	7/27/2024	Finalized: ☐ Temp Log: ☐	☑
METHYLENE BLUE (1%) (DIL) 10 MG/ML INJECTABLE				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $102.00 Last modified: 7/17/2024 by: BRENDA
Remaining 10

Note **rx+ stock- / br**

6/18/2024	500 ML	20241806@73	6/28/2024	Finalized: ☐ Temp Log: ☐	☑
MIDAZOLAM HCL IV 1 MG/ML INJECTABLE				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $300.00 Last modified: 6/18/2024 by: BRENDA
Remaining 500

Note **hospice- KC / br 1**

6/17/2024	25 GM	20241706@18	6/21/2024	Finalized: ☐ Temp Log: ☐	☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/17/2024 by: BRENDA
Remaining 10

Note **rx 6072346- KC BR5**

6/18/2024	5 GM	20241806@93	6/22/2024	Finalized: ☐ Temp Log: ☐	☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $120.00 Last modified: 6/18/2024 by: BRENDA
Remaining 5

Note **rx 6073068- cmk**

6/27/2024	30 GM	20242706@1	7/1/2024	Finalized: ☐ Temp Log: ☐	☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC				NIOSH	☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/27/2024 by: BRENDA
Remaining 15

Note **stock+ 2 rx- AM / br 5**

7/2/2024	5 GM	20240207@90	7/6/2024	Finalized: ☐ Temp Log: ☐	☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC				NIOSH	☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $120.00 Last modified: 7/2/2024 by: BRENDA
Remaining 5

Note **rx 6074059- cmk**

Date made	Qty made& units	Lot number	Beyond use date	Active
6/26/2024	5 GM	20242606@70	6/30/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $120.00 Last modified: 6/26/2024 by: BRENDA
Remaining 5
Note rx 6073590- cmk

6/24/2024 30 GM 20242406@26 6/28/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/24/2024 by: BRENDA
Remaining 25
Note STOCK+ MULTIPLE RX- AM/ BR 5

7/1/2024 10 GM 20240107@24 7/5/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 7/1/2024 by: BRENDA
Remaining 10
Note rx 6072371+6073152- ckm

7/1/2024 5 GM 20240107@119 7/5/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $120.00 Last modified: 7/1/2024 by: BRENDA
Remaining 5
Note rx 6074144- cmk

7/15/2024 5 GM 20241507@38 7/19/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $120.00 Last modified: 7/15/2024 by: BRENDA
Remaining 5
Note rx 6075026-cmk

7/16/2024 30 GM 20241607@101 7/20/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (CMPD) OINTMENT 0.04% OPHTHALMIC NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/17/2024 by: BRENDA
Remaining 30
Note rx+ stock- am/br5

6/25/2024 15 ML 20242506@30 8/9/2024 Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (PF) 0.025% INJECTABLE NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $375.00 Last modified: 6/25/2024 by: BRENDA
Remaining 15
Note STOCK+ RX- CMK

Date made	Qty made & units	Lot number	Beyond use date	Active
7/10/2024	70 ML	20241007@30	9/8/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN (PF) 0.04% INJECTABLE				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,100.00 Last modified: 7/12/2024 by: BRENDA
Remaining 70

Note **STOCK+ 2RX- AM / BR 5**

6/19/2024	500 ML	20241906@13	8/18/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN BLADDER SOLUTION 40 MG/40 ML (1 MG/ML) IRRIGATION				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,750.00 Last modified: 6/27/2024 by: BRENDA
Remaining 500

Note **stock+ DOCS- AM / br 5**

6/19/2024	500 ML	20241906@14	8/18/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN BLADDER SOLUTION 40 MG/40 ML (1 MG/ML) IRRIGATION				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,750.00 Last modified: 6/20/2024 by: BRENDA
Remaining 500

Note **stock+ DOCS- AM / br 5**

7/2/2024	500 ML	20240207@21	8/31/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN BLADDER SOLUTION 40 MG/40 ML (1 MG/ML) IRRIGATION				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $2,750.00 Last modified: 7/11/2024 by: BRENDA
Remaining 500

Note **stock- am / br 5**

6/24/2024	10 ML	20242406@23	7/8/2024	Finalized: ☐ Temp Log: ☐ ☑
MITOMYCIN GEL 0.04% OPHTHALMIC				NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/24/2024 by: BRENDA
Remaining 10

Note **rx 6068248- AM / br 5**

7/2/2024	42 ML	20240207@43	7/6/2024	Finalized: ☐ Temp Log: ☐ ☑
MORPHINE SULF+BUPIV+CLONID 50 MG+7.5MG+100MCG /ML SOLUTION				NIOSH ☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/3/2024 by: BRENDA
Remaining 42

Note **RX 20004905- AM / BR 5**

6/25/2024	205 ML	20242506@11	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
MORPHINE SULFATE (PF) (CMPD) 50 MG/ML INJECTABLE				NIOSH ☑

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $1,230.00 Last modified: 6/25/2024 by: BRENDA
Remaining -395

Note **stock- KC / autoclave**

Date made	Qty made& units	Lot number	Beyond use date	Active
7/17/2024	205 ML	20241707@29	8/31/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

MORPHINE SULFATE (PF) (CMPD) 50 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,230.00 Last modified: 7/17/2024 by: BRENDA
Remaining 205

Note **Stock- am/br5**

7/1/2024	45 ML	20240107@25	8/5/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

MUPIROCIN+MICONA+DEXA OTIC 2%+2%+0.1% SUSPENSION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $142.50 Last modified: 7/1/2024 by: BRENDA
Remaining 45

Note **rx 6067549- am /br5/prep**

6/18/2024	110 ML	20241806@65	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

NICOTINAMIDE ADENINE DINUCLEOTIDE 200 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/19/2024 by: BRENDA
Remaining 110

Note **4 rx- AM / br 2**

7/2/2024	24 ML	20240207@84	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

NICOTINAMIDE ADENINE DINUCLEOTIDE 200 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/2/2024 by: BRENDA
Remaining 24

Note **stock- MB / br 2**

7/8/2024	40 ML	20240807@58	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

NICOTINAMIDE ADENINE DINUCLEOTIDE 200 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/8/2024 by: BRENDA
Remaining 40

Note **rx+ stock- mb/ br 1**

7/11/2024	17 ML	20241107@10	8/10/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

OXYTOCIN NASAL SPRAY 150 UNITS/ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $204.00 Last modified: 7/11/2024 by: BRENDA
Remaining 17

Note **rx 6074487- am/br5**

7/5/2024	8 ML	20240507@20	8/19/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PAP+PHENT+PGE1+ATROP 30MG+2MG+40MCG+0.2 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/5/2024 by: BRENDA
Remaining 8

Note **rx 6074461- mb/am / br 1**

Date made	Qty made& units	Lot number	Beyond use date	Active
7/12/2024	10 ML	20241207@13	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 0.416MG+0.015MG+0.151MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $0.00 | Last modified: 7/12/2024 | by: BRENDA
Remaining 10

Note: rx 6058324- cmk___ / br___2

6/27/2024	15 ML	20242706@12	8/11/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+0.5MG+10MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | COLE | KAT
Cost $0.00 | AWP $270.00 | Last modified: 6/28/2024 | by: BRENDA
Remaining 15

Note: rx 6048286- _AM__ / br 2

6/20/2024	40 ML	20242006@20	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+1MG+10MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $720.00 | Last modified: 6/20/2024 | by: BRENDA
Remaining 40

Note: stock+ rx 6066828- _AM/mb/ br1

6/28/2024	60 ML	20242806@7	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+1MG+10MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $1,080.00 | Last modified: 6/28/2024 | by: BRENDA
Remaining 60

Note: rx 6073640+ stock-mb/ ___ / br 2

7/11/2024	50 ML	20241107@8	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+1MG+10MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $900.00 | Last modified: 7/11/2024 | by: BRENDA
Remaining 50

Note: stock+ rx- MB/ br 1

7/1/2024	8 ML	20240107@13	8/15/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+1MG+20MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $160.00 | Last modified: 7/1/2024 | by: BRENDA
Remaining 8

Note: rx 6073807- mb__ / br 1

6/19/2024	8 ML	20241906@9	8/3/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+1MG+25MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $152.00 | Last modified: 6/19/2024 | by: BRENDA
Remaining 8

Note: rx 6055209- am/mb/ br1

Date made	Qty made& units	Lot number	Beyond use date	Active
6/20/2024	15 ML	20242006@21	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+1MG+25MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $285.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	15			
Note	rx 6054453- KC / br 1			
6/28/2024	30 ML	20242806@6	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+1MG+25MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $570.00	Last modified: 6/28/2024	by: BRENDA	
Remaining	30			
Note	rx 6073511+ stock- mb/am / br 1			
6/27/2024	30 ML	20242706@7	8/11/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+1MG+30MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $540.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	30			
Note	rx 6073482- MB /br 1			
7/3/2024	8 ML	20240307@28	8/17/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+1MG+40MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $144.00	Last modified: 7/3/2024	by: BRENDA	
Remaining	8			
Note	rx 6074304 - AM /br 2			
7/17/2024	8 ML	20241707@28	8/31/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+2MG+20MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $160.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	8			
Note	rx 6050496- / br			
6/21/2024	15 ML	20242106@20	8/5/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+2MG+40MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $285.00	Last modified: 6/21/2024	by: BRENDA	
Remaining	15			
Note	RX + STOCK- mb/ / BR 2			
7/16/2024	15 ML	20241607@15	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑
PAPAV+PHENT+ALPROS 30MG+2MG+75MCG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $270.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	15			
Note	rx 6061090- mb/br 2			

Log report [detailed]

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	8 ML	20242406@28	8/8/2024	Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+3MG+100MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | COLE | KAT
Cost $0.00 | AWP $160.00 | Last modified: 6/24/2024 | by: BRENDA
Remaining 8

Note RX 6073441- KC/MB / BR 1

7/12/2024 | 8 ML | 20241207@9 | 8/26/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+3MG+100MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $160.00 | Last modified: 7/12/2024 | by: BRENDA
Remaining 8

Note rx 6054044- Am/ MB / br 1

6/17/2024 | 8 ML | 20241706@13 | 8/1/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS 30MG+3MG+500MCG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $200.00 | Last modified: 6/18/2024 | by: BRENDA
Remaining 8

Note rx 6072724- AM/KC / br 2

6/17/2024 | 8 ML | 20241706@29 | 8/1/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENT+ALPROS+ATROP 30MG+3MG+510MCG+0.2MG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $200.00 | Last modified: 6/18/2024 | by: BRENDA
Remaining 8

Note rx 6072758- KC / br 1

6/18/2024 | 10 ML | 20241806@40 | 7/23/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENTOL+ALPROS 25MG+2MG+750MCG/0.5ML GEL — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $0.00 | Last modified: 6/19/2024 | by: BRENDA
Remaining 10

Note rx 6071917- AM/MB / br 1

7/16/2024 | 10 ML | 20241607@16 | 8/20/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAV+PHENTOL+ALPROS 25MG+2MG+750MCG/0.5ML GEL — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $0.00 | Last modified: 7/16/2024 | by: BRENDA
Remaining 10

Note rx 6060006-mb/ br 2

7/5/2024 | 5 ML | 20240507@23 | 8/19/2024 | Finalized: ☐ Temp Log: ☐ ☑

PAPAVERINE+PHENTOLAMINE 30 MG+1 MG/ML INJECTABLE — NIOSH ☐

KOMM, PHAR CAITLIN | BLYMAN | MELANIE
Cost $0.00 | AWP $80.00 | Last modified: 7/5/2024 | by: BRENDA
Remaining 5

Note rx 6074206-cmk

Log report (detailed)

Date made	Qty made& units	Lot number	Beyond use date	Active
7/12/2024	8 ML	20241207@8	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PAPAVERINE+PHENTOLAMINE 30 MG+1 MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $128.00 Last modified: 7/12/2024 by: BRENDA
Remaining 8

Note rx 6055842- _am/_MB_/ br 2__

6/25/2024 5 ML 20242506@14 8/9/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PHENYLEPHRINE+LIDOCAINE IN BSS (PF) 0.75%+0.5% INJECTABLE

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $75.00 Last modified: 6/25/2024 by: BRENDA
Remaining 5

Note rx 6073527- KC/AM/br2

7/2/2024 60 ML 20240207@8 8/16/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PHENYLEPHRINE+LIDOCAINE IN BSS (PF) 1.5%+1% INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $900.00 Last modified: 7/2/2024 by: BRENDA
Remaining 60

Note stock+ baltimore washington surgery-mb/ _raj__ / br 1

7/10/2024 10 ML 20241007@4 7/20/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PILOCARPINE 0.25% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/10/2024 by: BRENDA
Remaining 10

Note rx 6050555- MB/br 1

6/21/2024 10 ML 20242106@15 7/1/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PILOCARPINE OPHTH 0.25% SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $60.00 Last modified: 6/21/2024 by: BRENDA
Remaining 10

Note rx 6073224- _MB__ / br 2

6/24/2024 1 ML 20242406@17 6/24/2025 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

POLYSORBATE 80 (STERILE)

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/24/2024 by: BRENDA
Remaining 0.6

Note for dexamethasone ointment- AM/BR5

6/21/2024 47 ML 20242106@22 7/5/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

PROGESTERONE IN OLIVE OIL 50MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $225.00 Last modified: 6/27/2024 by: BRENDA
Remaining 47

Note rx 6073759- _AM__ / oven

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/27/2024	15 ML	20242706@13	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHEN+ATROP 20UG+30MG+2MG+0.2MG/ML INJECTABLE

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $285.00 Last modified: 6/27/2024 by: BRENDA
Remaining 15

Note rx 6059784- am / br 2

7/3/2024 30 ML 20240307@8 8/17/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHEN+ATROP 20UG+30MG+2MG+0.2MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $750.00 Last modified: 7/3/2024 by: BRENDA
Remaining 30

Note stock+rx 6067489- am/ br 2

7/17/2024 40 ML 20241707@25 8/31/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHEN+ATROP 20UG+30MG+2MG+0.2MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,000.00 Last modified: 7/17/2024 by: BRENDA
Remaining 40

Note stock+ rx- /br

6/17/2024 50 ML 20241706@11 8/1/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHENT 11.8UG+18MG+0.6MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $600.00 Last modified: 6/18/2024 by: BRENDA
Remaining 50

Note stock- AM/BR1 / br

7/2/2024 60 ML 20240207@41 8/16/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHENT 11.8UG+18MG+0.6MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $720.00 Last modified: 7/2/2024 by: BRENDA
Remaining 60

Note stock- mb/ am / br 1

7/10/2024 60 ML 20241007@15 8/24/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHENT 11.8UG+18MG+0.6MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $720.00 Last modified: 7/11/2024 by: BRENDA
Remaining 60

Note stock- MB / br 1

6/19/2024 20 ML 20241906@3 8/3/2024 Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

PROS E1+PAPAV+PHENT 18UG+18MG+0.6MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $240.00 Last modified: 6/19/2024 by: BRENDA
Remaining 8

Note stock+ rx 6065549- AM/MB / br 1

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/28/2024	7 ML	20242806@10	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 18UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $108.00	Last modified: 6/28/2024	by: BRENDA	
Remaining	7			
Note	stock+ rx 6073893- cmk			
7/5/2024	20 ML	20240507@18	8/19/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 18UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $240.00	Last modified: 7/5/2024	by: BRENDA	
Remaining	20			
Note	stock+ 6060110- mb/am / br 1			
7/12/2024	30 ML	20241207@10	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 18UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $360.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	30			
Note	stock- AM / hr 2			
6/20/2024	90 ML	20242006@22	8/4/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 5.88UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $990.00	Last modified: 6/20/2024	by: BRENDA	
Remaining	90			
Note	stock+ rx- am/KC / br 1			
6/25/2024	120 ML	20242506@17	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 5.88UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $1,320.00	Last modified: 6/26/2024	by: BRENDA	
Remaining	120			
Note	stock- mb/am / br 2			
7/9/2024	120 ML	20240907@18	8/23/2024	Finalized: ☐ Temp Log: ☐ ☑
PROS E1+PAPAV+PHENT 5.88UG+18MG+0.6MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $1,320.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	120			
Note	stock- MB/rc/ hr 2			
6/26/2024	150 ML	20242606@29	8/10/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 1 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	0			
Note	stock- mb/ / br 1			

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
7/9/2024	160 ML	20240907@51	8/23/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 1 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/9/2024	by: BRENDA	
Remaining	-69.5			
Note	stock-mb/rc/br 2			
7/17/2024	180 ML	20241707@22	8/31/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 1 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/17/2024	by: BRENDA	
Remaining	180			
Note	stock- ___/ br__			
6/18/2024	100 ML	20241806@43	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 2 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	100			
Note	stock+ PFS- AM/KC/ br 1			
6/25/2024	150 ML	20242506@23	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 2 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	-111.5			
Note	stock+ pFs- KC/ MB/ br 1			
7/8/2024	160 ML	20240807@4	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 2 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	-180			
Note	stock- RC/ br 2			
7/16/2024	180 ML	20241607@6	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ 2 MG/ML SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	-45			
Note	stock- __rc_/ br 2___			
6/18/2024	87 EA	20241806@48	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
SEMAGLUTIDE INJ (PFS) 0.25 MG/0.25ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	87			
Note	stock+ rx- _AM__/ br _2__			

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
6/25/2024	100 EA	20242506@21	8/3/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.25 MG/0.25ML SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/25/2024 by: BRENDA
Remaining 100
Note **stock- AM/ br 2**

7/8/2024	138 EA	20240807@33	8/17/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.25 MG/0.25ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/11/2024 by: BRENDA
Remaining 138
Note **stock- rc/ br 2**

7/15/2024	140 EA	20241507@16	8/29/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.25 MG/0.25ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/15/2024 by: BRENDA
Remaining 140
Note **stock- RC/br 2**

6/21/2024	80 EA	20242106@17	7/29/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/21/2024 by: BRENDA
Remaining 80
Note **STOCK+ RX- AM / BR 1**

6/18/2024	73 EA	20241806@50	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/18/2024 by: BRENDA
Remaining 73
Note **multiple rx- mb br2**

6/27/2024	100 EA	20242706@14	8/11/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/27/2024 by: BRENDA
Remaining 100
Note

7/3/2024	46 EA	20240307@13	8/10/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/3/2024 by: BRENDA
Remaining 46
Note **stock- mb /br1**

Date made	Qty made & units	Lot number	Beyond use date	Active
7/9/2024	49 EA	20240907@27	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/9/2024 by: BRENDA
Remaining 49

Note stock- RC / br 2

7/12/2024	80 EA	20241207@17	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/15/2024 by: BRENDA
Remaining 80

Note stock- AM / br2

7/17/2024	20 EA	20241707@26	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 0.5 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/17/2024 by: BRENDA
Remaining 20

Note stock- /br

6/18/2024	131 EA	20241806@45	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 1 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/18/2024 by: BRENDA
Remaining 131

Note stock+ rx- KC / br 1

6/25/2024	100 EA	20242506@24	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 1 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/25/2024 by: BRENDA
Remaining 100

Note stock- MB/ br 1

7/2/2024	83 EA	20240207@35	8/16/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 1 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/5/2024 by: BRENDA
Remaining 83

Note stock- rc /br 2

7/12/2024	80 EA	20241207@16	8/26/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 1 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/12/2024 by: BRENDA
Remaining 80

Note stokc- MB / br 1

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
7/16/2024	85 EA	20241607@10	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 1 MG/0.5ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/16/2024 by: BRENDA
Remaining 85

Note **stock+ multiple rx- raj/ br 2**

6/19/2024	23 EA	20241906@15	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 2 MG/1ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/19/2024 by: BRENDA
Remaining 23

Note **stock- MB BR1**

6/27/2024	20 EA	20242706@32	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 2 MG/1ML SOLUTION

KOMM, PHAR CAITLIN COLE KAT
Cost $0.00 AWP $0.00 Last modified: 6/27/2024 by: BRENDA
Remaining 20

Note **rx 6069129- AM / br 2**

7/10/2024	20 EA	20241007@26	8/22/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 2 MG/1ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/10/2024 by: BRENDA
Remaining 20

Note **RX + STOCK- AM / BR 2**

7/16/2024	40 EA	20241607@11	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 2 MG/1ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/16/2024 by: BRENDA
Remaining 40

Note **stock+ rx- ____ / br ____**

7/17/2024	50 EA	20241707@27	8/30/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

SEMAGLUTIDE INJ (PFS) 2 MG/1ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/17/2024 by: BRENDA
Remaining 50

Note **stock+2rx- ____ /br ____**

6/19/2024	24 EA	20241906@7	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☑

SEMAGLUTIDE INJ PFS 1.7 MG/0.85 ML SOLUTION

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 6/19/2024 by: BRENDA
Remaining 24

Note **rx 6073064- mb br1**

Date made	Qty made& units	Lot number	Beyond use date		Active
6/25/2024	40 EA	20242506@22	8/3/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 1.7 MG/0.85 ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	COLE	KAT			
Cost $0.00	AWP $0.00	Last modified: 6/25/2024	by: BRENDA		
Remaining	40				
Note	stock- MB/ br 1				
6/27/2024	50 EA	20242706@10	8/9/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 1.7 MG/0.85 ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	COLE	KAT			
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA		
Remaining	50				
Note	stock- ___/ br___				
7/8/2024	50 EA	20240807@5	8/22/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 1.7 MG/0.85 ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $0.00	Last modified: 7/8/2024	by: BRENDA		
Remaining	50				
Note	stock+ rx- __RC_/ br 2				
7/12/2024	44 EA	20241207@15	8/26/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 1.7 MG/0.85 ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $0.00	Last modified: 7/12/2024	by: BRENDA		
Remaining	44				
Note	stock- CMK__/ br 2				
6/20/2024	24 EA	20242006@24	7/26/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 2.4 MG/0.75ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE			
Cost $0.00	AWP $0.00	Last modified: 6/21/2024	by: BRENDA		
Remaining	24				
Note	stock+ 2 rx- __AM__/ br 2				
6/19/2024	10 EA	20241906@83	8/3/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 2.4 MG/0.75ML SOLUTION				NIOSH	☑
CHILAKAPAT PRADEE	COLE	KAT			
Cost $0.00	AWP $0.00	Last modified: 6/19/2024	by: BRENDA		
Remaining	0				
Note	mb br1				
6/27/2024	30 EA	20242706@11	8/10/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 2.4 MG/0.75ML SOLUTION				NIOSH	☑
KOMM, PHAR CAITLIN	COLE	KAT			
Cost $0.00	AWP $0.00	Last modified: 7/9/2024	by: BRENDA		
Remaining	30				
Note	stock+ rx 6071756- MB/ br 1				

Date made	Qty made & units	Lot number	Beyond use date		Active
7/15/2024	200 EA	20241507@14	8/29/2024	Finalized: ☐ Temp Log: ☐	☑
SEMAGLUTIDE INJ PFS 2.4 MG/0.75ML SOLUTION				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/15/2024 by: BRENDA
Remaining 200

Note **stock+ 2 rx- mb/am / br 1**

7/5/2024	500 ML	20240507@73	7/15/2024	Finalized: ☐ Temp Log: ☐	☑
SODIUM CHLORIDE 0.9% INJECTABLE				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $116.67 Last modified: 7/5/2024 by: BRENDA
Remaining 500

Note **HOSPICE- AM/BR1**

7/5/2024	45 ML	20240507@49	1/1/2025	Finalized: ☐ Temp Log: ☐	☑
SSD+DEXAMETHASONE SUSP 1%+0.1% OTIC				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $135.00 Last modified: 7/5/2024 by: BRENDA
Remaining 45

Note **rx 6074411- _AM_ / prep/br5 (for dexamethasone)**

6/26/2024	200 GMS	20242606@28	12/23/2024	Finalized: ☐ Temp Log: ☐	☑
STERILE OPHTHALMIC OINTMENT				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $800.00 Last modified: 6/26/2024 by: BRENDA
Remaining 90

Note **stock/for mitomycin rx- __mb_ / oven**

7/8/2024	1000 ML	20240807@1	7/11/2024	Finalized: ☐ Temp Log: ☐	☑
SUPER IMMUNE BOOST EVERYTHING IV INJ				NIOSH	☐

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $250.00 Last modified: 7/8/2024 by: BRENDA
Remaining 1000

Note **RX 6074326- _MB__ / br 1_____**

7/10/2024	12 ML	20241007@14	8/7/2024	Finalized: ☐ Temp Log: ☐	☑
TACROLIMUS OPHTH AQ 0.02% EMULSION				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $84.00 Last modified: 7/11/2024 by: BRENDA
Remaining 12

Note **rx 6074743- MB / autoclave / BR 1**

7/10/2024	22 ML	20241007@10	8/7/2024	Finalized: ☐ Temp Log: ☐	☑
TACROLIMUS OPHTH AQ 0.03% EMULSION				NIOSH	☑

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $132.00 Last modified: 7/11/2024 by: BRENDA
Remaining 22

Note **2 rx- AM/MB / autoclave / BR 1**

Date made	Qty made & units	Lot number	Beyond use date	Active
6/24/2024	10 GM	20242406@8	7/22/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.03% OINTMENT				NIOSH ☑
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $100.00	Last modified: 6/25/2024	by: BRENDA	
Remaining	10			
Note	rx 6056374- AM / oven			
6/27/2024	10 ML	20242706@20	7/25/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.01% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	COLE	KAT		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	10			
Note	rx 6073817- mb / br 1			
7/10/2024	275 ML	20241007@6	9/8/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.03% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $1,168.75	Last modified: 7/11/2024	by: BRENDA	
Remaining	275			
Note	stock- MB / oven / BR 1			
7/2/2024	10 ML	20240207@23	7/30/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.1% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $75.00	Last modified: 7/2/2024	by: BRENDA	
Remaining	10			
Note	rx 6047564- am / br 1			
7/11/2024	10 ML	20241107@27	8/8/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.2% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $85.00	Last modified: 7/11/2024	by: BRENDA	
Remaining	10			
Note	rx 6065997- MB / br 1			
6/24/2024	10 ML	20242406@73	7/22/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.3% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $90.00	Last modified: 6/24/2024	by: BRENDA	
Remaining	10			
Note	rx 6071509- MB / br 1			
7/12/2024	10 ML	20241207@1	8/9/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.5% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $95.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	10			
Note	rx 6074415- MB / br 1			

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
7/16/2024	10 ML	20241607@17	8/13/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 0.5% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $95.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	10			
Note	rx 6069232- am /br 5			
7/11/2024	25 ML	20241107@9	1/7/2025	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC 2% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $237.50	Last modified: 7/12/2024	by: BRENDA	
Remaining	13.5			
Note	stock- am / oven			
6/26/2024	12 ML	20242606@13	7/24/2024	Finalized: ☐ Temp Log: ☐ ☑
TACROLIMUS OPHTHALMIC (MCT) 0.3% SOLUTION				NIOSH ☑
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $114.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	12			
Note	rx 6073647- am/ mb/br 1 / oven			
6/18/2024	12 ML	20241806@30	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
TIRZEPATIDE 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 7/2/2024	by: BRENDA	
Remaining	12			
Note	testing- mb/ / br 1			
6/18/2024	100 ML	20241806@31	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
TIRZEPATIDE 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/27/2024	by: BRENDA	
Remaining	100			
Note	testing- MB / br 1			
6/18/2024	100 ML	20241806@36	8/2/2024	Finalized: ☐ Temp Log: ☐ ☑
TIRZEPATIDE 15 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $0.00	Last modified: 6/18/2024	by: BRENDA	
Remaining	100			
Note	testing - / br			
7/12/2024	20 ML	20241207@77	8/11/2024	Finalized: ☐ Temp Log: ☐ ☑
TOBRAMYCIN OPHTH (FORTIFIED) 15 MG/ML SOLUTION				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $120.00	Last modified: 7/12/2024	by: BRENDA	
Remaining	20			
Note	stock- MB / br 1			

Date made	Qty made& units	Lot number	Beyond use date	Active
7/11/2024	150 ML	20241107@13	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

TROPICAMIDE+PHENYLEPHRINE 1%+2.5% OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/12/2024 by: BRENDA
Remaining 150

Note wang- AM / br 2

7/5/2024	26.66 ML	20240507@74	8/19/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

VANCOMYCIN SOLN 25 MG/ML OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $151.07 Last modified: 7/5/2024 by: BRENDA
Remaining 26.66

Note STOCK+ RX- CMK

7/8/2024	30 ML	20240807@6	10/8/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

VITAMIN B COMPLEX (REPACK) 100 INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/8/2024 by: BRENDA
Remaining 30

Note stock- rc/ br 2

6/18/2024	5 ML	20241806@51	6/22/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

VITAMIN D3 100,000 IU/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $75.00 Last modified: 6/18/2024 by: BRENDA
Remaining 5

Note rx 6071025- mb/ /br 2

7/1/2024	5 ML	20240107@3	7/5/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

VITAMIN D3 100,000 IU/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $75.00 Last modified: 7/1/2024 by: BRENDA
Remaining 5

Note rx 6071025- mb/ / br 1

7/11/2024	20 ML	20241107@54	8/25/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

VORICONAZOLE (GEN) 1 % OPHTHALMIC

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $0.00 Last modified: 7/11/2024 by: BRENDA
Remaining 20

Note rx 6074990- AM / br 2

7/15/2024	420 ML	20241507@6	7/29/2024	Finalized: ☐ Temp Log: ☐ ☑ NIOSH ☐

XYLAZINE 200MG/ML INJECTABLE

KOMM, PHAR CAITLIN BLYMAN MELANIE
Cost $0.00 AWP $1,785.00 Last modified: 7/16/2024 by: BRENDA
Remaining 420

Note rx 6075126- am/mb / autoclave/ br 3

Log report (detailed)

Date made	Qty made & units	Lot number	Beyond use date	Active
7/15/2024	420 ML	20241507@8	8/12/2024	Finalized: ☐ Temp Log: ☐ ☑
YOHIMBINE 10 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $840.00	Last modified: 7/16/2024	by: BRENDA	
Remaining	420			
Note	rx 6075125- mb/ autoclave/br 3			
7/9/2024	375 ML	20240907@20	8/6/2024	Finalized: ☐ Temp Log: ☐ ☑
YOHIMBINE 2 MG/ML INJECTABLE				NIOSH ☐
KOMM, PHAR CAITLIN	BLYMAN	MELANIE		
Cost $0.00	AWP $375.00	Last modified: 7/9/2024	by: BRENDA	
Remaining	375			
Note	18 rx- _MB__/ autoclave			

352 logs in report

Total cost $0.00

Total price $99,321.64

4.024 SHIPPING AND VALIDATION FOR COMPOUNDED PREPARATIONS

Authorized by: **Date:**

1.0 PURPOSE

1.1 The purpose of the standard operating procedure is to describe the general procedure for verifying shipping conditions of Compounded Preparations at SaveWay Compounding Pharmacy.

2.0 SCOPE

2.1 Shipping and Receiving personnel are responsible for monitoring and recording weather conditions.

2.2 This SOP is directed toward the Shipping and Receiving Department and Customer Service Representatives (CSRs) but must be followed by all personnel at SaveWay Compounding Pharmacy (SWCP).

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and is responsible for employee training.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Monthly for one year and then quarterly or as needed with extreme changes in weather.

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate packaging supplies (e.g., cushioned envelope, small boxes, packaging paper, bubble wrap)

- **7.1.1** Designated bin/area set up appropriately for prescriptions to be shipped
- **7.1.2** Ice packs (for possible storage and/or shipping)
- **7.1.3** Patient's information (address, phone number)
- 7.1.4 Shipping labels
- 7.1.5 Plastic thermometer
- 7.1.6 F.4.024.1 Shipping Validation Log

8.0 GENERAL INFORMATION

8.1 SaveWay Compounding Pharmacy ships to locations outside of our own premises. Shipping Personnel shall select modes of transport that are expected to deliver properly packed compounded preparations in undamaged, sterile, and stable condition to recipients.

8.2 Compounding personnel should ascertain that temperatures of compounded preparations during transport by the selected mode will not exceed the warmest temperature specified on the storage temperature range on compounded preparation labels. It is recommended that shipping and receiving personnel or compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that compounded preparations may encounter.

8.3 Compounding personnel shall include specific handling an exposure instruction on the exteriors of containers packed with combative preparations to be transported and obtain reasonable assurance of compliance therewith from transporters.

8.4 Management at the compounding facility shall periodically review the delivery performance of couriers to ascertain that the compounded preparations are being efficiently and properly transported.

8.5 Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and packaging integrity of compound preparations. Although compounding personnel routinely performed many of the tasks associated with these functions, some tasks, such as transport, handling, and placement into storage, may be fulfilled by non-compounding personnel. The performance of the non-compounding personnel is monitored for compliance to established policies and procedures.

9.0 PROCEDURE

9.1 A successful shipping verification procedure ensures that compounded preparations that require refrigeration, remain at the recommended temperature until delivered at their destination.

9.2 In extreme heat or cold conditions, the shipping validation procedure shall be performed as well to ensure that compounded preparations that require refrigeration, remain at the recommended temperature until delivered at their destination.

9.2.1 Designated shipping personnel shall check the weekly weather forecast to monitor for extreme heat (over ninety-five degrees Fahrenheit) or extreme cold (below thirty-two degrees Fahrenheit).

9.3 Monthly or as needed for extreme heat or cold, the Quality Assurance Officer shall perform a shipping validation. The steps to perform this are as followed:

9.3.1 Pack a plastic thermometer, a fattibase placebo suppository, 1ml amoxicillin/clavulanate transdermal gel, and a 30ml potassium bromide solution into an appropriately sized foil shipping pack. The size and number of ice packs needed is dependent on the weather conditions. Use the following guidelines to determine the size and quantity of ice pack needed:

9.3.1.1 95 degrees or greater – 2 X 24oz and a Styrofoam cooler
9.3.1.2 80-94 degrees – 2 X 24oz
9.3.1.3 70-80 degrees – 1 X 24oz & 1 X 16oz
9.3.1.4 Less than 70 degrees – 2 X 16oz
9.3.1.5 ** For Tablet Triturates only – 1 X 8oz

9.3.2 Seal the foil pack and place into an appropriately sized cardboard box.

9.3.3 Seal the box with shipping tape.

9.3.4 Place the sealed box into the trunk or a vehicle for seventy-two hours.

9.3.5 Once the seventy-two hours have been completed, remove the sealed box from the trunk of the vehicle, unpack the thermometer, and record the temperature on the appropriate sheet.

9.4 If the shipping validation process fails, then additional ice pack and shipping materials shall be used with each refrigerated compounded preparation. If the temperature is too extreme to where it potentially can harm a compounded preparation or the patient, then it

shall be the decision of the Director of Operations to hold all refrigerated shipping or find an alternate route of delivery.

9.5 **Shipping of Prescriptions**

9.5.1 Courier Companies

9.5.1.1 United Postal Service (UPS) is the designated courier for the shipping of prescriptions.

9.5.1.2 Under certain conditions, such as arrival time, cost, distance to be shipped, or clients with a Post Office Box or at the patients/ caregiver's request may a prescription be shipped via the United States Postal Service (USPS).

9.6 **Area Setup**

9.6.1 Prescriptions that must be shipped are transported to the shipping department after they are paid, filled, and checked.

9.6.2 Shipping personnel are responsible for processing items to be shipped throughout the day.

9.6.3 Shipping personnel must check all departments at least 30 minutes prior to the courier pickup time to check for prescriptions that must be shipped.

9.7 **Prescription Shipping**

9.7.1 When compounded preparations are distributed to locations outside the premises of SaveWay Compounding Pharmacy where they are compounded, compounding personnel select packaging containers and materials that are expected to maintain physical integrity, stability, and stability of compound preparations during transit. Packaging is selected based on environmental conditions so that it simultaneously protects compounded preparations from damage, leakage, contamination, and degradation, and protects personnel who transport packaged compounded preparations from harm.

9.7.2 SaveWay Compounding Pharmacy ships compounded preparations to locations outside their own premises and shall select modes of transport that are expected to deliver properly packaged compounded preparations in undamaged, sterile, and stable condition to recipients.

9.7.3 Each prescription to be shipped will be indicated with either "CC/Ship", "Inv/Ship", or "SR/Ship" at the time of prescription/ refill intake.

9.7.4 Final check must be performed on the prescription.

9.7.5 Place the prescription in either the bin for awaiting payment or the bin awaiting a shipping label.

9.7.6 The shipping charge for prescriptions is $12.00 in addition to the cost of the prescription.

9.7.6.1 Orders $150.00 and over are exempt from the shipping charge.

9.7.6.2 Sterile items will be charged the shipping charge regardless of cost.

9.7.7 If the shipment is for a medical office and requires it to be delivered the next day, then the office shall be charged the actual shipping cost rounded to the nearest whole dollar rather than the standard $12.00.

9.7.8 Confirm the invoice reflects the correct cost for shipping. If the invoice needs to be adjusted, then it must be given to the bookkeeper.

9.7.9 Tightly close and ensure that the prescription is spill-proof and that all needed patient/caregiver administration supplies are included with the prescription. (I.E suppository inserts, Transdermal information sheets, syringes, bottle inserts, etc.)

9.7.10 Complete a shipping label to include the pharmacy's name and address on the label and the patient's name and delivery information, perform final check of information confirming that the shipping label is correct.

9.7.11 New patients/caregivers that have not had a prescription shipped to them previously, must be contacted to verify shipping information prior to the prescription being shipped.

9.7.12 Place the prescription in the appropriate shipping container, which may include insulated bubble mailers, Styrofoam, or other temperature-resistant containers.

9.7.12.1 Critical requirements are that packaging integrity must protect the compound in preparation. Inappropriate transport and handling can adversely affect the quality of certain compound preparations having unique stability concerns.

9.7.12.1.1 Secure packaging must prevent the depression of syringe plungers or dislodging of syringe tips during handling and transport.

9.7.12.1.2 Liquids shall be placed plastic in zip-loc bags in case of leakage during transport.

9.7.12.1.3 Transdermal gels must be protected from extreme cold during transport.

9.7.12.1.4 Hazardous Drug (HD) substances in compounded preparations require safeguards to maintain the integrity of the compound preparation and to minimize the exposure potential of these preparations to the environment and two personnel who may come in contact with them. Special requirements associated with the packaging, transport, and handling of these agents include the prevention of accidental exposures or spills and the training of personnel in the event of an exposure or spill.

9.7.12.1.4.1 Examples of special requirements of these agents include exposure reducing strategies such as the use of luer lock syringes and connections, syringe caps, the capping of container ports, sealed plastic bags, impact resistant containers, and cautionary labeling.

9.7.13 Shipping personnel shall periodically review the delivery performance of couriers to ascertain that compounded preparations are being efficiently and properly transported.

9.7.14 Shipping personnel should ascertain that temperatures of compounded preparations during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on combative preparation labels. It is recommended that shipping personnel communicate directly with the couriers to learn shipping durations and exposure conditions that compound preparations may encounter.

9.7.15 Shipping personnel shall include specific handling and exposure instructions on the exteriors of containers packed with compound preparations to be transported and obtain reasonable assurance of compliance therewith from transporters.

9.7.15.1 Add ice packs if applicable. Guidelines for ice packs are as follows;

9.7.15.1.1 95 degrees or greater – 2 X 24oz and a Styrofoam cooler

9.7.15.1.2 80-94 degrees – 2 X 24oz

9.7.15.1.3 70-80 degrees – 1 X 24oz & 1 X 16oz

9.7.15.1.4 Less than 70 degrees – 2 X 16oz

9.7.15.1.5 ** For Tablet Triturates only – 1 X 8oz

9.7.16 After carefully packaging the compounded preparation, seal the shipping container.

9.7.17 Affix the shipping label onto the appropriate shipping container.

9.7.18 Place a piece of shipping tape over the patient/ caregiver shipping information to prevent any damage to the label that could result in shipping errors.

9.7.19 Medications that are being shipped next day air must be set aside and not placed with the packages being sent by way of ground shipping.

9.7.20 Once all prescriptions that require shipping have been processed and completed, shipping personnel must print the "End of Day" report. This report must be signed by the UPS driver then filed in the appropriate area.

9.8 Timing

9.8.1 Make sure that shipments of temperature-sensitive items are not shipped over the weekend. ***CAUTION: Exposure to temperature extremes for prolonged periods may have negative results to certain preparations.***

9.9 Confirmation

9.9.1 Notify the patient when they may expect their prescription at the time of intake. If the shipping destination is within 150 miles of SaveWay Compounding Pharmacy, then typically it is delivered the next day. This is not guaranteed, and SaveWay Compounding Pharmacy personnel must not guarantee delivery unless guaranteed next day delivery is requested from the patient/ caregiver.

10.0 ATTACHMENTS

10.1 N/A

11.0 History

11.1 Original. Daniel Joyce. 8-15-16
11.2 Edited. Brenda Poland. 8-21-16
11.3 Reviewed. Brenda Poland. 8-31-18
11.4 Edited. Brenda Poland. 04-15-2021
11.5 Reviewed. Brenda Poland. 12-06-2022
11.6 Reviewed. Brenda Poland. 11-15-2023

F.4.024.1 Shipping Validation Log

Week of	Actual Forecast Temp. M /T /W / Th/ F	Max Forecast Temp. M / T / W / Th / F	Pass/ Fail	QAO Initials	RPH Initials
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4.016 FINAL CHECK

Authorized by: **Date Effective:**

1.0 PURPOSE

1.1 This standard operating procedure (SOP) describes the process of performing final checks on compounded preparations at SaveWay Compounding Pharmacy. Certain quality criteria must be met before releasing a preparation to be dispensed.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at SaveWay Compounding Pharmacy (SWCP).

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure personnel training.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

5.0 DEFINITIONS

5.1 CoA—Certificate of Analysis

5.2 CNSP—Compounded Nonsterile Preparation

5.3 CSP—Compounded Sterile Preparation

5.4 QA—Quality Assurance is a system of procedures, activities, and oversight that ensures the compounding process consistently meets quality standards.

5.5 QC—Quality Control is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before the release of a CNSP/CSP.

6.0 FREQUENCY

6.1 With each prescription or compounded preparation

7.0 EQUIPMENT & SUPPLIES

7.1 LED flashlight

7.2 Black and/or white background

7.3 Visual Audits

8.0 GENERAL INFORMATION

8.1 The safety, quality, and performance of compounder preparations depend on the correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment.

8.2 As a final check, the compounder must review each procedure in the compounding process.

8.3 To ensure accuracy and completeness, the compounder must observe the finished preparation to ensure that appear as expected in must investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient

9.0 PROCEDURE

9.1 The compounder must check the procedure at each stage of the process. Where possible, a trained second person should verify each critical step in the compounding process.

9.2 At the completion of compounding, before releasing and dispensing, the CNSP or CSP must be visually inspected to determine whether the physical appearance is as expected.

9.2.1 Some visual characteristics to observe would be color, texture, physical uniformity, particle size, smoothness, etc.

9.3 This SOP discusses the established written procedures that describe the tests or examinations conducted on the compound in preparation to ensure their uniformity and integrity.

9.4 Appropriate control procedures have been established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.

9.5 Staff pharmacists must perform a final check on each prescription and/or compounded preparation, checking for the following, as applicable.

9.5.1 Logs of formulas created using compounded software

9.5.1.1 Calculations

9.5.1.2 Lot numbers, manufacturer, beyond-use dates, and expiration dates

9.5.1.3 Printouts of scale weights

9.5.1.3.1 Hand recorded volumes of non-dry ingredients

9.5.1.3.2 For sterile compounding, the syringes used to measure wet ingredients should have the plunger pulled back and kept with the log until the final check.

9.5.1.4 Bubble point testing—for CSPs aseptically sterilized by filtration.

9.5.1.5 Technician's signature/initials

9.5.2 All of the following must be included in the final check, as applicable.

9.5.2.1 Patient

9.5.2.2 Patient information

9.5.2.2.1 Phone, address, date of birth

9.5.2.2.2 Medical condition, medication allergies

9.5.2.3 Drug

9.5.2.4 Strength

9.5.2.5 Directions

9.5.2.6 Quantity

9.5.2.7 Refills

9.5.2.8 Doctor

9.5.2.9 DEA Number

9.5.2.10 Prescription expiration

9.5.2.11 Beyond-Use-Date (BUD)

9.5.2.12 Dosage Form

9.5.2.13 Packaging

9.5.2.14 Auxiliary Labels

9.5.2.15 Necessary supplies

9.5.2.15.1 Inserts or adapta caps for liquids

9.5.2.15.2 Dosing syringe

9.5.2.15.3 Finger cots

9.5.2.15.4 Appropriate applicator

9.5.2.15.5 Handouts

9.5.3 Visual inspection of prescriptions

9.5.3.1 Color and appearance (e.g., cloudiness or phase separation) as well as the following:

9.5.3.1.1 Suspensions are examined for uniform particle size and even distribution and the ability to resuspend upon shaking

9.5.3.1.2 Solutions are examined for clarity

9.5.3.1.3 Treats are examined for fullness and wholeness and proper texture

9.5.3.1.4 Capsules are examined for fullness and lack of damage to capsule shell.

9.5.3.1.5 Creams, ointments, and gels are examined for smoothness and consistency.

9.5.3.1.5.1 Cream should not be broken.

9.5.3.1.6 Transdermal gel syringes are examined for air bubbles, cracking and fullness

9.5.3.1.7 Suppositories, troches, and tablet triturates are examined for fractures or cracking and fullness

9.5.3.2 Quality release checks are an important mechanism through which a final assessment of the overall quality of a finished CNSP or CSP is made. There are multiple checks and balances that must occur during the compounding process to ensure the preparation was made correctly.

9.5.3.3 Final quality release checks must be documented on the compounding record via signature of the pharmacist on duty.

9.5.3.4 SWCP personnel responsible for performing final quality release checks on CSPS must be properly trained.

9.5.3.5 Any CSP failing quality release checks must be quarantined and segregated from others, so it is not dispensed erroneously.

9.5.3.6 Aseptic processing compounding personnel and staff pharmacists at SWCP have the responsibility to ensure through a series of in process and finished process checks, continued compliance with USP Chapter <797>. Elements of Quality Release Checks for CSPs include:

9.5.3.6.1 Component selection

9.5.3.6.1.1 Compounding personnel must ascertain before use that components for CSPS are of correct identity, appropriate quality, within expiry date and have been stored under appropriate conditions.

9.5.3.6.1.2 CoAs must be reviewed to ensure the accuracy, identity and purity of all bulk nonsterile components used in the preparation of CSPs.

9.5.3.6.1.2.1 Calculations must be performed to ensure accuracy of potency of final preparation.

9.5.3.6.2 Staffing oversight is critical during compounding activities

9.5.3.6.2.1 Compounding personnel present the greatest opportunity for variability in the process and subsequent opportunity for microbial contamination. This is especially true during aseptic processing.

9.5.3.6.2.2 Due to risk of microbial control, those that oversee compounding personnel must ensure that the compounding personnel follow facility SOPs for

hand hygiene and garbing and clean room behavior as any deviations from acceptable practice may result in contaminated CSPs.

9.5.3.6.3 Environment

9.5.3.6.3.1 Environmental monitoring (EM) and personnel monitoring (PM) facilitate early detection of contamination and its source.

9.5.3.6.3.2 Personnel performing quality checks must be aware of the state of control of the facility in which the CSP was made.

9.5.3.6.4 Equipment and supplies

9.5.3.6.4.1 Equipment used in compounding must be of suitable condition such that the surfaces that contact components are not reactive, additive, or sorptive.

9.5.3.6.4.2 Equipment must be stored in a manner that facilitates its use, maintenance, and cleaning for compounding operations.

9.5.3.6.5 Weights and volume

9.5.3.6.5.1 Weight and volume measurements of ingredients should be obtained and documented, with secondary review verification by a compounder prior to preparation. This can be done by an in person visual verification or camera system in order to capture what is actually being measured and mixed.

9.5.3.6.5.2 The compounding record must be reviewed and double checked to ensure accurate documentation.

9.5.3.6.6 Filter integrity testing

9.5.3.6.6.1 Filter integrity testing, or bubble point testing, is required if nonsterile to sterile compounding is performed and the solution is sterilized with a sterilizing filter. Every sterilizing filter must be tested before the CSP is dispensed to ensure the filter has not been compromised.

9.5.3.6.6.2 The results of the filter integrity testing must be recorded on the compounding record.

9.5.3.6.7 Visual inspection

9.5.3.6.7.1 USP 797 requires 100% visual inspection of CSPS at the time of labeling and before dispensing and again if the CSPs are stored for more than a day before dispensing.

9.5.3.6.7.2 Visual inspection of CSPs can be enhanced by using a magnifying glass, a white and black background, LED lighting and other mechanisms That provide visual aid.

9.5.3.6.7.3 In addition to examining the actual CSP For proper color, clarity, odor, cloudiness, precipitation, or particulates, the inspector must also review labeling and container closure integrity.

9.5.3.6.7.4 Sterility and endotoxin testing results must be reviewed by the quality control officer (QCO) before a CSP is released.

9.5.3.6.7.5 CSPs are dispense before receiving the results of their sterility test, there must be a written procedure requiring daily observation of the incubating test specimens (See SOP 6.008 Sterility Testing and SOP 4.025 Biological Indicators) and an immediate recall of the dispensed CSP when there is any evidence of microbial growth in the test specimens. In addition, the patient and physician of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk.

9.5.3.6.7.6 All injectable and IV infusion CSPs made from non-sterile ingredients must undergo endotoxin testing or assigned a BUD of 72 hours (3 days).

9.5.3.6.8 Sterile compounded solutions must be inspected for visible particulate matter. In the event of finding particulates, the compounded preparations must be rejected, quarantined, disposed of, and not dispensed.

9.5.3.6.8.1 Best practice when examining for particulates is to wear gloves, to not leave fingerprints obscuring the visual inspection.

9.5.3.6.8.2 Hold the vial by the top and gently swirl the contents, rotating in a circular motion (air bubbles will rise and particles will sink to the bottom of the container).

9.5.3.7 Proper storage and handling requirements must be noted and followed.

9.5.4 Quality checks that result in a failure must be investigated to determine the root cause. Investigation results should be used to identify weaknesses, revise SOPs, retrain staff, reduce errors, and identify areas of improvement (processes, equipment, aseptic technique, environment, etc.)

9.5.5 Corrections and improvements must be documented as part of the investigation and filed according to documented procedure. Documentation of quality release checks provides evidence that every CSP was reviewed to ensure it is free from defects and has all the expected quality characteristics.

9.5.6 When the final check is complete, the pharmacist must sign off on the formula log or worksheet, the original prescription, and/or initial off on the prescription labels/receipt attached to the dispensing bag.

10.0 ATTACHMENT

10.1 **N/A**

11.0 HISTORY

11.1 Original. Kristen Akers. 07-26-2015.
11.2 Edited. Brenda Pavlic. 10-20-15
11.3 Reviewed. Brenda Pavlic. 11-10-15
11.4 Reviewed. Brenda Poland. 08-31-18
11.5 Edited. Brenda Poland. 04-15-2021
11.6 Edited. Brenda Poland. 12-06-2022
11.7 Reviewed. Brenda Poland. 11-15-2023

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2360

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)			
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? *If no, go to compliance statements.*	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. *Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.*	Yes		4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. *Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."*	Yes		2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. *Inspector note; Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."*	Yes		3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. *Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."*	Yes		6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. *Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."*	Yes		4.2, 11
1.6	**Equipment:** The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). *Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."*	Yes		6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. *Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."*	Yes		6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. *Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."*	Yes		7.1, 11

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. *Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."*	Yes		9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. *Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."*	Yes		11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. *Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."*	Yes		1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. *Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."*	Yes		11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. *Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."* *If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.*	Yes		11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. *Inspector note: Per USP, "The facility must have procedures in place to:* *• Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)* *• Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy* *• Investigate if other lots are affected and recall if necessary* *An SOP for recall of dispensed CNSPs must contain:* *• Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall* *• Procedures to determine the distribution of any affected CNSP, including the date and quantity of distribution* *• Procedures to identify patients who have received the CNSP* *• Procedures for disposal and documentation of the recalled CNSP (and)* *• Procedures to investigate and document the reason for recall."*	Yes		12.1
	Designated Person(s) and Personnel Training Program. Inspector must complete the <795> Records Review module to complete this section.			

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to the compliance statements.***		Christine Keenan CPHT; Brenda Poland QM	1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes	; Brenda Poland QM	1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes	Brenda Poland QM; 4th quarter annual	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes	Brenda Poland QM	1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes	PIC	1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes	NS RPH	1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes	QM	1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes	QM	1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes	Final Checks	2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes	Training Files	2, 14

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Safeway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel,"*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes	Training Files	2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area, ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes	NS Staff RPH	
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes	NS.Staff RPH	3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. *Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."* *If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.*	Yes	Temp and humidity recorded in Simplifi	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. *Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."*	Yes	Simplifi Report	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. *Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.* *Monitoring devices are typically calibrated or replaced.*	Yes	PIC	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. *Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."*	Yes	continuous monitoring; PIC determines action	4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
10.0	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? *Record in the Inspector Notes.*	[redacted]	21 degrees celcius	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? *If no, go to compliance statements.*	YEs		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? *Inspector note: This is a USP recommendation.*	Yes	Distilled Water delivered from spray bottles	4.3 USP <1231>

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>, <800>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
Area 1	**Cleaning and Sanitizing**			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		Cavacide every Friday. Bleach floors weekly, IPA 70% daily	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	YEs	Daily, weekly, monthly	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the beginning of each shift on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the end of each shift on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized between compounding CNSPs with different components.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes	All purpose cleaner daily	5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes	monthly	5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	yes		5
Area 2	**Equipment and Components**			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	CVE's in HD (2) Powder containment hoodds in NS lab (3)	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Safeway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. *Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."* *If no, inspector should describe observations.*	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. *Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:* *- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;* *• CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;* *• Under the work surface of a BSC is cleaned and sanitized at least monthly; and* *- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.* *If no, inspector should describe observations.*	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). *Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.*	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). *If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.*	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. *If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.*	yes	Quantus every 6 months	6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* *If no, go to compliance statements.*	yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. *If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.*	Yes		6.2.1

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National Association of Boards of Pharmacy®
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Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

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Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes	EIR	6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes	SWFI	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	SWFI	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	YEs		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations (797), 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	YEs		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	YEs		6.2.3, 6.2.4

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? *Inspector note: This is a USP recommendation.*	yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? *If no, go to compliance statements.*	yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	yes	file and electronic	6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes	Feb-24	6.2.5, 14

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		Observation	Inspector Notes	USP Reference(s)
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		8.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		8.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 8.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) *Inspector should review a minimum of five (5) MFRs and five (5) CRs.*			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to the compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Buy2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	yes		7.2, 6
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	yes		2, 7.2, 8
	Labeling			

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Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Safeway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? *If no, go to compliance statements.*	yes		9
31.1	Information on the label is prominently and legibly displayed. *Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."*	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. *If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.*	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? *Inspector note: This is a USP recommendation.*	yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? *Inspector note: This is a USP recommendation.*	yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? *Inspector note: This is a USP recommendation.*	yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CSNP was to be sent outside of the facility or health care system? *Inspector note: This is a USP recommendation.* *If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A.*	yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? *Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."* *If no, go to compliance statements.*	yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1

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Nonsterile Compounding Inspection for USP <795>

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Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. *Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.6 Extending BUDs for CNSPs apply."*	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? *Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.* *If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.*	yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? *If no, who establishes the maximum BUD for a MFR?*	yes	PIC	7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	yes		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? *If no, go to compliance statements.*	yes		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	Yes	online/ PIC	10.5
40.2	CNSPs are prepared in accordance with the USP monographs. *If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.*	Yes		10.5
40.3	Components used by the compounder match those listed in the monograph. *If no, describe the source of the component in monograph and the source that the pharmacy used.*	Yes		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. *If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.*	Yes		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? *Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.* *If no, go to compliance statements.* *If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.*	yes		10.4
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. *Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a $Aw \geq 0.6$, eg, emulsions, gels, creams, solutions, sprays, or suspensions.* *If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to; the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	yes		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. *Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a $Aw \geq 0.6$, eg, emulsions, gels, creams, solutions, sprays, or suspensions.* *If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to; the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	yes		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. *Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a $A_w < 0.6$. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.* *If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to; the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	yes		10.4 Table 4 USP <659>

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Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days, ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days, ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	yes		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	No	cited from USP monographs	10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	YEs		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	yes		10.5

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	yes		10.5
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	yes	bracketed studies	10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	yes		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	yes		12.2

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
47.1	The pharmacy has a complete written or electronic record of each complaint made. *Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."*	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. *Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."*			12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.			1.1.3, 12.2

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

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Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? *Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.* *Review most recent recall and describe in the Inspector Notes.* *If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.*	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? *If no, go to compliance statements.*	yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? *Inspector note: This is a USP recommendation.*	yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? *If no, go to compliance statements.*	yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	yes		13.1
	Compounding Personnel Observations *Inspector must observe personnel performing compounding and related activities. This section will not require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with no creams or other drugs) as long as all observations can be viewed.*			
53.0	Personal Preparation Observation: Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? *If no, go to compliance statements.*	yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	yes		3.1
54.0	Hand Hygiene Observation: Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	*Garbing Observation:* Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.			
58.0	Compounding Observation: Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		8.2 (8.2.1 - 8.2.5)

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Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	Final CNSP check observation: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	yes		8, 8.1, 9
59.1	CSNP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Saveway Compounding Pharmacy

e-Profile ID:

Inspection Date: 3/4-3/5 2024 Michelle McCreary, Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CSNP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	yes		12
61.0	Cleaning and Disinfection Observation: Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation),	Yes		8.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Universal Inspection Form

Hazardous Drugs - Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs - Handling in Health Care Settings inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
	General Information and Scope;		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	SOP F.9.001.5 (list)
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	Yes	SOP F.9.001.5 (list)
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	NO	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	Yes	
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	Yes	SOP F.9.001.5 (list)
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	No	

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
List of Hazardous Drugs			
	Total Non-Compliant (Includes Unknowns)	0	
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	F.9.001.5
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	April Annual
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	NA	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);		
8.02	Dosage form;		
8.03	Risk of exposure;		
8.04	Packaging;		
8.05	Manipulation; and		
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.		
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*		

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		Finding	Notes
	Personnel Responsibilities		
	Total Non-Compliant (Includes Unknowns)	0	
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	Christine Keenan DP; Brenda Poland QM
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	QM
	Documentation and Standard Operating Procedures (SOPs)		
	Total Non-Compliant (Includes Unknowns)	0	
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		9.001
10.01	**Receiving:** Contacting HD residues on packaging, work surfaces, floors	Yes	9.003, 9.009
10.02	**Dispensing:** Counting or packaging tablets and capsules	Yes	9.008
10.03	**Compounding/other manipulations:** Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	9.008
10.04	**Administration and other patient care activities** (if applicable).	NA	
10.05	**Spills:** Spill generation, management, and disposal.	Yes	9.006

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
10.06	**Transport**	Yes	9.003
10.07	**Waste:** Collection and disposal of HD waste and trace contaminated waste	Yes	9.005
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	QM-4th quarter annually
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	both
13.00	SOPs address at a minimum:		
13.01	Hazard communication program plan	Yes	9.001
13.02	Competent personnel	Yes	9.004
13.03	Occupational safety program	Yes	9.007
13.04	Designation of HD areas	Yes	signage
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	9.009
13.06	A list of HDs	Yes	F.9.001.5
13.07	Storage of HDs	Yes	HD Rooms
13.08	Compounding of HDs	Yes	HD Negative pressure

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		Finding	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	9.008
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	CNSP 9.010; CSP 9.011
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents Used: Bleach, Hydrogen Peroxide	Yes	9.014
13.11.02	Dilutions, if used	Yes	
13.11.03	Frequency	Yes	Daily,weekly,monthly,PRN
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	9.010; 9.011
13.11.05	Documentation requirements	Yes	9.008
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	9.009
13.13	If a shipping container appears damaged and **does not need to be opened:**		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	9.009
13.13.02	Labeled as "hazardous"; and	Yes	

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		Finding	Notes
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened:**	[redacted]	
13.14.01	Container is sealed in plastic or an impervious container;	Yes	9.009
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	yes	
13.14.03	container is placed on a plastic-backed preparation mat;	yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	Yes	
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	9.007
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

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e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delawore

		Finding	Notes
13.19	Administering SOPs, if applicable	Yes	9.003
13.20	Environmental monitoring (eg, wipe sampling) SOPs	Yes	QTR
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	9.005
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	9.006
13.22.02	Responsible person for handling spills;	Yes	Christine Keenan DP
13.22.03	Location of spill kits and clean-up materials;	Yes	9.006
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	will develop SOP

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e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	9.001
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	9.009
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	F-9.001.1
	Personnel Training —*Check four employee files for documentation*		
	Total Non-Compliant (Includes Unknowns)	**0**	
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	

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		Finding	Notes
18.00	For non-sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	F.9.001.4.2
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	F.9.001.4.2
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	Compounding personnel
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	9.010; 9.011
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	9.008

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		Finding	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	9.014
23.06	Response to known or suspected HD exposure;	Yes	9.013
23.07	Spill management;	Yes	9.006
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	yes	Concentra
	Personal Protective Equipment		
	Total Non-Compliant (Includes Unknowns)	0	
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	9.010; 9.011
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	yes	
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	

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		Finding	Notes
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	NA	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	9.014
26.08	Spill control;	Yes	9.006
26.09	Waste disposal; and	Yes	9.005
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	NA	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	NA	All disposable
29.00	**Gloves:** The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 – *or its successor* – and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation:** *Are chemotherapy gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?*		
29.02	Chemotherapy gloves are powder-free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	

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		Finding	Notes
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	Yes	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation:** Are *chemotherapy gloves changed every 30 minutes [unless otherwise recommended by the manufacturer]?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	
30.00	**Gowns:** The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

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		Finding	Notes
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection:** The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.	Yes	
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	Concentra
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	

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		Findings	Notes
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	Yes	
33.05	Other (describe in notes).	Yes	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	
35.03	Full-facepiece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	yes	
35.05	Other (describe in notes).	yes	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE:** Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	

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		Finding	Notes
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	yes	
	Facilities and Engineering Controls		
	Total Non-Compliant (Includes Unknowns)	0	
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	
39.02	Storage of HDs	Yes	negative HD room
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	negative HD room
39.04	Sterile HD compounding (if performed by the pharmacy)		Negative buffer room 5
40.00	***Recommendation:*** *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	NO	Future
41.00	**Receipt:** Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	
41.01.01	Neutral	X	
41.01.02	Negative		
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C-SEC).	Yes	
43.00	**Storage:** Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	HD room
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	NA	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.	Yes	Hd room
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	Quantus
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C-SCA]).	Yes	HD room

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		Finding	Notes
44.04	**Recommendation:** *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	Yes	
45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non-HD inventory, there is a written policy/SOP addressing it.	NA	
46.00	**Compounding:** There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C-PEC located in a C-SEC room.	Yes	
47.01	The C-SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	HD CNSP room; Buffer Room 5
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	Monitored daily
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01-54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):	[redacted]	HD room negative pressure
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	Yes	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N	
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding:**	[redacted]	
50.02.01	Class I biological safety cabinet (BSC)		
50.02.02	Class II BSC		
50.02.03	Containment ventilated enclosure (CVE)	X	
50.02.04	Compounding aseptic containment isolator (CACI)		
50.02.05	Other, describe		
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):	[redacted]	
51.01	Is externally vented *(preferred)* ; **and/or**		
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	X	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	N	
52.01	Is **nonsterile HD compounding** only "occasional"? *If yes, please describe frequency and quantity.*	NA	

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Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	NA	
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	NA	
53.00	The C-SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01-61.02.03. If no, skip to 62.	Yes	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding:**		
55.01.01	CACI		
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)		
55.01.03	Class II BSC, Type A2 (formerly Type B3)	x (three)	
55.01.04	Class II BSC, Type B1		
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)		
55.01.06	Class III BSC		
55.01.07	LAFW (not for antineoplastics)		
55.01.08	CAI (not for antineoplastics)		
56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	Yes	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	Yes	

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e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?	NA	
58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?	NA	
59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	NA	
59.01	The C-SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	Quantus
59.02	A handwashing sink is at least one meter or more away from the C-PEC	Yes	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA	[redacted]	Anteroom 3 (outside)
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	Yes	
60.01	The buffer room has fixed walls.	Yes	
60.02	The buffer room is externally vented.	Yes	
60.03	The buffer room has HEPA-filtered supply air.	Yes	
60.04	The buffer room has at least 30 ACPH.	Yes	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	Yes	

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Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
60.06	The anteroom has fixed walls.	Yes	
60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.	Yes	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	Yes	
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	Yes	
61.00	If the negative-pressure HD buffer room is entered through a positive-pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	Yes	ISO 7 ante Room (+) ISO Buffer Room (-)
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	Yes	
61.02	Indicate how HD contamination is minimized:		sealed in zip loc chemo bags
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	Yes	
61.02.02	Use of sealed containers	Yes	
61.02.03	Other, *describe*		

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e-Profile ID:
Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:		Quarterly
62.01	Interior of C-PEC and equipment within the C-PEC	Yes	
62.02	Pass-through chambers	NA	not used
62.03	Surfaces in staging or work areas near the C-PEC	Yes	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	Yes	
62.05	Areas immediately outside the HD buffer room or the C-SCA	Yes	
	Receiving		
	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	**Recommendation:** HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.		
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	

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Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	Christina Keenan
	Labeling, Packaging, Transport, and Disposal		
	Total Non-Compliant (Includes Unknowns)	**0**	
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport:	Yes	

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		Finding	Notes
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	Yes	
	Dispensing, Packaging, and Compounding Processes		
	Total Non-Compliant (Includes Unknowns)	0	
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation:** When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	Yes	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle-generating activities, such as crushing, opening capsules, and weighing powders.	Yes	
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
	Total Non-Compliant (Includes Unknowns)	0	
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	

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		Finding	Notes
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*		
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.	Yes	
81.00	Areas, other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compramised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
	Total Non-Compliant (Includes Unknowns)		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	

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Inspection Date: 3/4-3/5/2024; Michelle McCreary, Pharmacist Complaince Officer State of Delaware

		Finding	Notes
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)			
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes	Brenda Poland QM	1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes	11/15/2023	2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note; Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, go to compliance statements.***	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).	Yes	Category 2 only currently	1.5

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Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is	Yes	Training Files	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***	Yes	SOP 4.038 (reviewed)	3, 3.3
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	Yes		4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.	Yes	Quantus (certifier)	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.	Yes	Excel Spreadsheet (completed daily)	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.	Yes	2005 (SOP)	7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.	Yes	Chapter 5	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.	Yes	4.022 SOP	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.	Yes	4.002 SOP	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.	Yes	4.016 SOP	12, 18, 20

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2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.	Yes	4.011 SOP	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.	Yes	4.005 SOP	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***	Yes	1.005 SOP	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes	4.005 Sterilization SOP; 4.008 Depyrogenation SOP	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***	N/A	Cat 2 only	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes	4.031 SOP; AST; ********** BR6 only	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	N/A		21
3.0	**CSPs: Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived**			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?	N/A	No immediate use	1.3

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4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.***	N/A	Category 2 only at this facility	1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	Yes	Training Files	1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	Yes		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	Yes		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to the compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	No		1.4

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		Observation	Inspector Notes	USP Reference(s)
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only compounds sterile preparations (eg, does not prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.		NA; NO IMMEDIATE USE	1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.		NA; NO IMMEDIATE USE	1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	Yes	4.031 SOP	1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	Yes	BR6 ONLY; HEP B SERIES; OSHA TRAINING; TEARS FOR DRY EYE	1.1.2
	Facility Design and Engineering Controls			
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 , Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	Yes		4.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A	No SCA	4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A	NO SCA	4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2

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		Observation	Inspector Notes	USP Reference(s)
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	Cleanroom Suite: Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes	SOP SIGNEAGE	4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes	monitored and recorded	4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes	Quantus reports	4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes	ANTE ROOM 3 ISO 7	4.1.2, 4.2.1

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12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes	Qunatus Reports	4.1.2, 4.2.1, 4.2.3
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes	Electronic File	4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom, ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes		4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes	cauk	4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes	CRP	4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1

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12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes	easily cleanable	4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are PECs used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes	6 Buffer Rooms	4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3:** PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes	CATEGORY 2 ONLY	4.2.3 Table 5

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14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A	NO CACIs or RABS	4.2.3 Table 5
15.0	Are CAIs/CACIs (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A	NO CACIs or RABS	4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1

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		Observation	Inspector Notes	USP Reference(s)
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	Yes	More than 6 ft from entrance	4.4
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes	More than 5 ft from BR entry	4.4

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Training of Personnell	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	auto locking mechanism	4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes	Cleaning SOP reviewed	4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes	No Tacky mats	4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes	No Cardboard	4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes	Cleaned	4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** *If no, go to compliance statements.*	Yes	Simplifi Complaince Software	4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes	Contract with HVAC to maiintain	4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes		4.2, 9.3.4, 19.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes	Simplifi Reports	4.2, 9.3.4, 19.1
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note; Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.*** ***CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	PIC sends for Calibration every 12 months	4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Alarm - alterted when out of range; HVAC checks	4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No	Only a few days not long periods of time	4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	No	Stored in ISO 8 Prep Room	4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	Yes	66 degrees F	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	Yes	46 degrees F Relative humidity	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 6th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes	Pressure differential 0.0709; ANTE to unclassified 0.2..	4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes	Manual daily checks and electronic; continuous monitoring	4.2.1, 4.2.5, 5
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes	SOP 2.009 8.1.1	4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	Yes		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	Yes		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	Yes		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	Yes		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes	Category 2 only currently	4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes	HD only; Prep ISO 7 room ISO 8 or better; Prep CVE; Sterile steps BSC	4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes	Quantus	5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20

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Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes	Brenda Poland QM	4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes	Sept 2023 due and scheduled end of March 2024	4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20

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Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional -- Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH).** ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement. If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms,	Yes		4.2.5, 5

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Sterile Compounding Inspection for USP<797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm HEPA filter integrity).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.12	**PEC; (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes		4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC; Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC;** All PEC HEPA filters were leak tested (to confirm HEPA filter integrity). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
33.16	PEC: All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.17	PEC-IVLFZ: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	Yes		4.2.3
33.18	If a robotic enclosure is used as the PEC, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that; 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A <u>unless</u> the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	N/A	no equiptment in PEC	5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes	2.009 SOP	6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2

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Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes	Quantus	6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes	EM SOP 2.004	6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes	EM SOP 2.009	6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes	SOP 2.009	6, 6.1, 6.2
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes	SOP 2.009	6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes	SOP 2.009	6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes	Daily each compounder	6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes	Quantus to send out and also done in house	6.2.2

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes	in house and quantus	6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab.*** ***If no, describe observations.***	Yes		6.2.2
40.0	Are processes for sampling and monitoring air quality for viable airborne particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***	Yes	EM SOP	6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the frequencies specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes	>797; monthly	6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes	Annually	6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes	TSA-3; Sab DEX; PDA-F	6.2.2 Box 5

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Facility Name: Saveway Compounding Pharmacy
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		Observation	Inspector Notes	USP Reference(s)
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m³/device** **ISO Class 7: >10 cfu/m³/device** **ISO Class 8: > 100 cfu/m³/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes	Excel spredsheet	6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note; Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes	MIDI Labs Newark, DE	6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring surfaces for viable particles in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***	Yes		6.3

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e-Profile ID:
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		Observation	Inspector Notes	USP Reference(s)
41.1	Surfaces and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1
41.2	Surfaces within the cleanroom suite and SCA are sampled at the frequencies specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes	Map >797	6.3, 6.3.1, 14.4.2
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes	TSA-3; Sab DEX; PDA-F	6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 6th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days. If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes	MIDI Labs Newark, DE	6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	Training and oversight	3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note; Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes	Sterile Dept Staff Pharmacist or QM	3, 3.1

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes	2.013 SOP	3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A	ONLY DISPOSABLE GARB USED NO REUSABLE GARB IS PERMITTED	3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A	Category 2 only currentlhy	3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is laundered and resterilized with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes	>797	2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes		2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A	Non sterile for media fill	2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A	non sterile and sterilize filter and incubate	2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>, ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes		Box 2
	Cleaning and Disinfection			
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint.	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners EPA-registered disinfecting agent(s) to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to; phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved. Per USP, inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Pre Empt; Hypo Chlor; Peridox, Sterile IPA 70%	7.1.1 Box 7 <1072>

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Sterile Compounding Inspection for USP <797>

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e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate EPA-registered sporicidal agent(s) to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes	Peridox. Pre Empt, Hypo Chlor, Sterile IPA 79%	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes	DC in 28 Days in ISO 7/ 5	7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water, ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***	Yes		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes	Simplifi	7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes	Start, between and at finish	7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes	Hypo Chlor	7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes	Weekly	7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly, ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.0	Does the pharmacy's documented application of sporicidal disinfectant on surfaces comply with the frequencies specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes	Simplifi	7.2, 14.4.2 Table 10
48.1	Sporicidal disinfectant is applied to all interior surfaces of the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes	weekly / monthly	7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes	Hypo Chlor (bleach concentrate diluted with SWFI) Peridox Monthly	7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Monthly	7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Monthly	7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Monthly	7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes	No SCA	7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes	Daily weekly andmontly cleaning recorded in Simplifi	7.2 Table 10

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharmacist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
	Components			
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***	Yes	all filler, excipients, non active API's	9.3
50.1	**APIs:** APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes	All COA's strored electronically and printed/ stored ina physical file	9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well, If the API comes from a repackager, the pharmacy must be able to confirm <u>the manufacturer</u> of the API was registered as an Establishment with FDA.***	Yes	EIR (Established inspection report)	9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes	Same suppliers	9.3.1

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Sterile Compounding Inspection for USP<797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes	2ml and 5ml vials	9.3.1, 9.3.2, 9.3.3
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3
	Equipment and Supplies			9

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e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes	Equipment file of all with Red Lion	9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes	Red Lion; Safety Inc for autoclave and dryheat oven; Brandywine Scales for scales	9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes	Calibrate pumps with each use	9.1

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		Observation	Inspector Notes	USP Reference(s)
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes	Outer Room	6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20°C-25°C and 30°C-35°C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Recorded in Simplifi	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation The inspector *must* observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding areas. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes	non worn to work	3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered,	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes	not permitted	3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes	currently no persons needing accommodations	3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes	SOP	3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes	SOP	3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes	SOP	3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes	SOP	3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes	Lint free towels only	3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	hair, head cover, face mask, bunny suit, gown, shoe covers	3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA.	Yes	ISO 8 Prep/Ante	3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, Inspector should answer statement as N/A.***	Yes	All garb and gowns not reused	3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; Inspector should answer statement as***	N/A	No reusable gowns permitted	3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Cyclosporine and Tacrolimus Emulsion 2%+0.05% opth observed via camera compounders not aware	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2

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		Observation	Inspector Notes	USP Reference(s)
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes	6 buffer Rooms	4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as; preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to compliance statements.***	Yes		15

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Sterile Compounding Inspection for USP<797>

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		Observation	Inspector Notes	USP Reference(s)
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes	Discarded immediately after use	15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes	Date marked on vial	14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	Semaglutide 1mg/ml 10 finished vials inspected; cyclosporine 6 vials inspected, EDT 3%/3.33ml debride for surgery - 8 vials inspected	12

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder (to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes	Recorded in Simplifi	7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes	entire sterile lab	7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes	Alpha mop heads	7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes	Pre-Empt, Peridox, Sterile IPA, Hypochlor	7.1.1
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes	Top to bottom back to front	7.1.2 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used, ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7
	Sterilization and Depyrogenation			10
63.0	Does the pharmacy compound preparations with any nonsterile starting components?	Yes	API's	10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10

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		Observation	Inspector Notes	USP Reference(s)
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes	Pharmacy grade filters, bubble point test every filter	10.2 USP <1229.4>
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***	Yes	See filter chart	10.2

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes	Recorded on Formula	10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	Yes	Autologous Serum Tears	10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes	Maintained by Red Lion	10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	Yes	3rd party testing	10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	Yes	distilled	10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	Yes	0.5 micron used	10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	Yes		10.3 USP <1229.1>

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		Observation	Inspector Notes	USP Reference(s)
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	Yes		10.3 USP <1229.5> USP <1229.9>
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	Yes	Tape attached d to formula worksheet	10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	Yes		10.3, 20
67.0	Dry Heat Sterilization: Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	Yes		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	Yes	0.5 micron used	10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	Yes		10.4

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Sterile Compounding Inspection for USP<797>

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e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	Yes	150 degrees celcius X 2.5 hrs w/ BI	10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	Yes		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	Yes	Manual checks throughout cycle	10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	Yes		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	Yes		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	Yes	B I Strips	10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	Yes	also chemical sterilize	10.1 USP <1228.4>
A11	**Master Formulation and Compounding Records** Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.			11
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to A14compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20

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Sterile Compounding Inspection for USP <797>

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Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes	Per USP 797 Category BUDS	11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	N/A	No immediate use	11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes	PK Logged Formula	11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes	MB12	11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10

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Sterile Compounding Inspection for USP <797>

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Inspection Date: March 4th and 6th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes	MB12	13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes	PK Label	13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>
	Establishing BUDs			14
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes	Hard stop in software	14.3

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		Observation	Inspector Notes	USP Reference(s)
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1** CSPs prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that do not undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes	SOP 6.020	14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable)** are performed and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that do not undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, Table 13

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
73.7	**Category 2 CSPs:** BUDs for terminally sterilized Category 2 CSPs where sterility testing and endotoxin testing (if applicable) are performed and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 80 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A	MB12/ Cyclosporin/Tacrolimus	14.3, 14.2.1, 14.2.3, Table 13

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes	Hard stop in software	14.3
75.0	Are BUDs for Category 3 CSPs assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A	Cat 2 currently	14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	Yes		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3 Table 15

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 6th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A	No Category 3	14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>
76.0	Are multiple-dose CSPs prepared in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes	Cat 2 currently	14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes	Cat 2 currently	14.5

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes		14.5
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	N/A	Per note not required as it is patient specific for one patient one dose	14.5 USP <51>
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note; Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes	for Cat 3 only in future	14.5 USP <1207>
	Finished Preparation Release Checks and Tests			12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order,	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes	SOP 4.016	12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes	USP 71 via ARL	12.2
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, If the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes	ARL requires will not test otherwise	12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3

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		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	Yes	USP 71 via ARL	12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure effect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes	SOP 6.004	12.2
79.0	For any CSPs assigned BUDs that require bacterial endotoxin testing, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes	SOP 6.016	12.3

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Sterile Compounding Inspection for USP <797>

Facility Name: Saveway Compounding Pharmacy
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		Observation	Inspector Notes	USP Reference(s)
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	Yes		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all injectable Category 2 CSPs compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes	SOP 6.016	12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all injectable Category 3 CSPs compounded from one or more nonsterile components.	Yes		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes		12.2, 12.3
	CSP Packaging, Shipping and Transport			19
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	SOP 4.005	19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes	SOP 4.024	19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes	SOP 4.024 and4.035 (ship and delivery)	19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes	SOP 4.024 and 4.035	19.3
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	SOP 6.001	18 USP <1163>

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Facility Name: Saveway Compounding Pharmacy
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		Observation	Inspector Notes	USP Reference(s)
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes	SOP 6.009	18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes	SOP 6.015	18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of; adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes	Chapter 6 SOP	18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes	Brenda Poland QM	18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes	Brenda Poland QM	18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes	Complaint file SOP 6.009	18.2, 18.3, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Savoway Compounding Pharmacy
e-Profile ID:
Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).***	Yes	Complaint form	18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes	SOP 6.015	18.1, 18.2
83.0	If a CSP is dispensed or administered before the results of release testing are known, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to compliance statements.***	Yes	SOP 6.015 and 9.13-9.15	18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes	6.015 and 9.15.7 SOP	18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes	6.015 and 9.14.2 SOP	18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes	SOP 6.015 and 9.14.3	18.1
	Personnel Training and Evaluation Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns G-J) for details.***	Yes	SOP F.4.004.1	2.2, 20 Box 1, Table 1

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Inspection Date: March 4th and 5th 2024; Michelle McCreary Pharamcist Compliance Officer

		Observation	Inspector Notes	USP Reference(s)
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns K-O) for details.***	Yes	SOP F- 4.002.1	2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns P-S) for details.***	Yes	SOP 3.001	2, 2.1, 17 Table 2, Table 3

SAVEWAY
COMPOUNDING
PHARMACY, LLC

July 19, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: New Pharmacy Application for Saveway Compounding Pharmacy, LLC

Dear Board Members:

Enclosed is our New Pharmacy Application for Saveway Compounding Pharmacy, LLC ("SaveWay"). SaveWay is a wholly-owned subsidiary of Myonex, LLC ("Myonex"). Myonex, LLC is a subsidiary (97.1% owned) of Myonex Holdings, Inc. ("Myonex Holdings"). Out of an abundance of caution, we have included Personal History Applications for each of the following individuals:

Robert Cohen, who is an officer of SaveWay, Myonex, and Myonex Holdings and an owner (30%) of Myonex Holdings.

Michael Cohen, who is an officer of SaveWay, Myonex, and Myonex Holdings and an owner (34.95%) of Myonex Holdings.

James Lovett, who is an officer of SaveWay and Myonex.

Greg Lavin, who is an officer of SaveWay, Myonex, and Myonex Holdings.

The remaining portion of Myonex Holdings is owned 20% by a trust, for which Michael Cohen is the trustee and primary beneficiary, and by other trusts, none of which owns more than 10% individually.

Furthermore, this letter shall serve as confirmation that **Pradeep Chilakapati** (Pharmacist-in-Charge for SaveWay) is authorized to appear before the Board of Pharmacy on behalf of SaveWay as SaveWay's designated representative. Attached is a Written Consent of the Sole Member of Saveway Compounding Pharmacy, LLC evidencing my status as an officer of SaveWay.

Thank you in advance for your time and consideration of our New Pharmacy Application.

Sincerely,

Greg Lavin
Chief Financial Officer

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04110	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Veterinary compounding	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FG0344767 ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: veterinary

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

Physical Address: 8 Digital Drive, Suite 104

City: Novato State: CA Zip: 94949

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 415-455-5590 Toll Free # (NAC 639.708, NRS 639.23286): 888-855-6337

Fax: 415-455-9039 Contact Email: brvlicensing@bluerabbit.vet

Website: www.bravacare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Trisha Petticrew

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23084

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Trisha Petticrew	NV Pharmacist Registration #: 23084
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Wedgewood Holdings Inc

Corporation/Organization Name: Wedgewood Pharmacy LLC

Mailing Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Email: licensing@wedgewoodpharmacy.com

Contact Person Name: Joe Costa

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/COO (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph Costa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Joseph Costa hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President/COO (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15th day of April, 2024

Samantha Botnick
Notary Public

Samantha L Botnick
NOTARY PUBLIC
State of New Jersey
ID # 50130085
My Commission Expires
June 25, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Costa, President/COO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/15/2024
Date

Board Use Only	Date Received: 4/17/24	Amount: $500 check 55861

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD VILLAGE PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



Jeffrey W. Bullock, Secretary of State

5944344 8300

SR# 20241174280

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203115229

Date: 03-26-24

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 2/2/2023 Inspector: Denise Dukatz

Firm: BRAVA CA LLC Phone: ___

Address: 8 DIGITAL DR STE 104 City: NOVATO Zip: 94949

Ownership: CORPORATION

Permit #: PHY58192 Permit Exp: 5/1/2023 DEA#: FG0344767 DEA Exp: 9/30/2024

Date of Self Assessment Form: 6/20/2021 Other Permit #: /N/A Date of DEA Inventory: ___

Hours M-F: 8am-6pm Hours Saturday CLOSED Hours Sunday: CLOSED

PIC ERIK M CLAUSEN RPH60873 Administrator ___

RPH Consultant ___

Staff	RPH Name:	License #:
	REBECCA M LEE	RPH75586
	STEPHEN A CRAWFORD	RPH72636
	TRUMAN H CHEUNG	INT44934
	ALAN P CHAN	RPH59202
	TRISHA R PETTICREW	RPH77807
	REBECCA E WILD	RPH73324
	MARJORIE ANNE G CHENG	RPH75020

Staff Name:	License #:
AMANDA L SUMMERFIELD	TCH122031
ARVIN A DULZURA	TCH140488
HALEY J BAXLEY	TCH182341
JANINE C GERMAN	TCH130852
KAELEEN T BAJET	TCH173845
KRISTINE G CHAW	TCH167296
MELISSA V CASTILLO	TCH180282
NATHANIEL A GABRIEL	TCH184904
QUANISHA M SMITH	TCH156346
RUBEN B BAUTISTA JR	TCH121980

Inspector Remarks:

Community Veterinary Compounding Pharmacy, warehouse
Compounding: yes, approximately 200 per day
Deliveries: yes, UPS, USPS, notice to consumer of their right to consultation, phone number and hours of operation prints out with each delivery and is placed in the delivery container.
Licensed in 49 other states

Routine Inspection, COVID-19:
Pharmacist-in-Charge Erik Clausen, present during inspection

Remarks:
Security
Hot and cold running water: yes
Notice to consumer Poster, posted in view of the public: yes

1 NA

Language translation poster posted in view of the public: yes
PHY License posted in public view: yes
Offsite storage waiver, yes, #228648 and # 227647
Refrigerators/freezers and room temperature electronically monitored by: Traceable, alerts are sent via email and text.
Power of Attorney: yes
Biennial Inventory: 12/30/2022
CII reconciliation report: last on: 12/30/2022 (performed audit from June to December, they are aware it is a quarterely requirement).
Controlled substances perpetual inventory
Quality Assurance Report: last from 12/20/2022.
Community Pharmacy self-assessment: 6/20/2021
Compounding self-assessment: 6/20/2021
C2 and C3-5 Invoices, filed separately and signed by a Pharmacist
Wholesaler: Medisca, Fagron, Letco, PCCA, MWI (division of Amerisource Bergen), Cardinal Health
Reverse Distributor: Pharmalogistics
Waste: Barnett Medical
Prescription label is patient centered
Opioid warning label: warning of risk of overdose or addiction on controlled substance prescripiton, it prints out on the prescription label.
DEA 106: None
CSOS: used for ordering CII controlled substances.
References: IJPC, Compounding Today, PCCA, Trissels, Plums
Reviewed dispensed controlled substance paper prescriptions, CII and CIII-CV
Policies and Procedures: job descriptions, Non-sterile Compounding, temporary absence of a pharmacist, language translation services and theft/impairment, recalls, performance improvement, quality assurance program, employee training, Cytotoxic or hazardous drug spills, garb,

Compounding:
Description of modular compounding area: anteroom leads to hazardous compounding room with 2 exhausted BSC IV Hoods, and two non-hazardous compounding rooms. One NH compoudnig room has six powder hood and a pass through, and the other NH compounding room has two powder hoods.
Batch compounding of non-sterile compounded drug products. controlled substances, hazardous (NIOSH Table 1-3) and non-hazardous compounding.
Hoods: certified by ENV Services anually, last on 8/23/2022. All ten hoods passed.
Master Formulas: reviewed methimazole 5mg/ml suspension, methimazole 2.5mg/0.1ml transdermal pen, Maropitant 10mg/ml suspension, Ursodiol 90mg capsule
Compounding records: reviewed lot #520019, for: Methimazole 5mg/ml suspension, Lot #538757, Methimazole 2.5mg/0.1ml transdermal pen, Lot#539859, Maropitant 10mg/ml suspension, Lot 539469, Ursodiol 90mg capsule.
Prescription label reviewed: The type appears smaller than 12-point Sans Serif typeface, please check with Pharmedika, CCR 1707.5 (a)(1). There are no storage instructions as required by CCR 1735.4(a)(3) and the date compounded is not listed as required by CCR 1735.4(a)(5).
Quality Assurance testing: 8/12/2022 gabapentin 100mg/ml, 94.9% potency.
On-going competency evaluation: TCH Melissa Castillo and RPH Alan Chan. Hazardous chemical acknowledgement. Competency evaluation in the past year, includes potency test of compounded drug.
Cleaning records: Pestle software.
Cleaning agents: 70% IPA, Saniwipes, Clorox wipes, Hydrogen Peroxide

Pressure, temperature and humidity records: reviewed
Annual review of compounding policies and procedures by the PIC, last on and around 9/2021. PIC aware it has been over a year. The policies and procedures are currently in review.
Eye wash stations

Discussion/Education:
1) **California Code of Regulations Section 1732.5 – Pharmacist Renewal Requirement:** Pharmacist are required to complete 2 of the 30 hours of Continuing Education in the prior 24 months to renew their pharmacist license by participation in a Board provided CE course in Law and Ethics. The two hours of continuing education are currently posted on the board's website at www.pharmacy.ca.gov. Pharmacist renewing their licenses which expires on or after July 1, 2019 are subject to this requirement. Print certificate of completion after online course is completed and maintain for four years.Available on Board's website:
http://www.pharmacy.ca.gov/licensees/webinars/law_ethics.shtml.
2) Recommend reviewing USP 795, which becomes official and enforceable on 11/1/2023.
3) Recommend not compounding hazardous compounded drug products until the hazardous compounding room has been certified to have at least 12 air changes per hour and maintain negative pressure in the range of (-0.01-0.03" water column). On top of modular room the fan motor has a red light today. Fan or motor may have stopped working today. The pressure was last checked at 930am today and was -0.03" water column.
4) Recommend labeling the compounded drug quarantine area (currently red "on-hold labels placed on quarantined compounded drugs which are placed in an area away from active inventory, a green label is then placed on the compounded drugs over the red label when they are approved and released for use).
5) Recommend revising cleaning document for area where pharmacists work, it states they are cleaning compounding work surfaces.
6) Recommend revising SOP 6.004 for non-sterile compounding finished preparation testing, as it states all compounded products shall be quarantined until documentaiton of results of release testing and inspections are complete which is not the current practice.

Corrections/Violations:
1) CCR 1735.4(a)(3): There are no storage instructions on the compounded drug prescription label.
2) CCR 1735.4(a)(5): The date compounded is not listed on the compounded drug prescription label.
3) CCR 1735.6(e)(1): Hazardous non-sterile compounding room does not have the number of air changes per hour documented by a certification company.
4) CCR 1735.63(e)(2): Hazardous non-sterile compounding room had positive pressure on the ENV cerification report from 4/7/2022 (0.0343" water column), instead of negative pressure. During the inspection, the room had positive pressure noted by PIC and Inspector by feeling airflow on hands coming out of the vent in the door to the room and the magnahelic gauge read 0.01" positive pressure. However, the print out of the electronic pressure was -0.03 " water column today at 9:34.
5) CCR 1735.3(a)(2)(F): The compounding records reviewed showed the manufacturer does not always print out under the ingredients used in compounding the drug product. For ingredients compounded in house, please be sure they state (compounded in house or similar).
6) BPC 4076.7: Opioids are dispensed without a warning of risk of overdose and addiction.

"Pursuant to Business and Professions Code 4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of corrections, for an office conference with the board's executive officer to contest the order of correction."

Please send the action item(s) and remedial actions for the corrections/violations with 14 days, by close of business

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

on **2/16/2023.**

Denise Dukatz, Pharm D.
Inspector
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: 415-629-9319
Fax: 415-242-6219
Email: denise.dukatz@dca.ca.gov

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form.

Pharmacist (sign) _____

Pharmacist (print) Erik Clausen

Inspector (sign) Denise Dukatz

Inspector (print) Denise Dukatz

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 2/2/2023 Permit #: PHY58192

Time of Day: 12:58 PM

Name as shown on permit: **BRAVA CA LLC**

Address: 8 DIGITAL DR STE 104 City: NOVATO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1735.3(a)(2)(	Recordkeeping for Compounded Drug Preparations . For each compounded drug preparation, the pharmacy records shall include: A compounding log consisting of a single document containing all of the following: The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. In that, at the time of inspection, lot 538757, Methimazole 2.5mg/0.1 transdermal pen did not list a manufacturer for the methimazole on the compounding record. In addition, lot 520019, for methimazole 5mg/ml suspension, did not list the manufacturer for anhydrous suspending vehicle (compounded in house), lot 539859, for maropitant 10mg/ml suspension did not list the manufacgturer for anhydrous suspensing vehicle.
2. CCR 1735.4(a)(5)	Labeling of Compounded Drug Preparations. Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least: The date compounded; and In that, at the time of inspection, rx: 616014, for compounded drug: Pimobendan 5mg capsules does not list the date compounded.
3. CCR 1735.4(a)(3)	Labeling of Compounded Drug Preparations. Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least: Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included; In that, at the time of inspection, rx: 616014, for compounded drug: Pimobendan 5mg capsules did not list storage instructions.

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4. CCR 1735.6(e)(1)	Compounding Facilities and Equipment. Hazardous drug compounding shall be completed in an externally vented exhausted physically separate room with the following requirements: Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and In that, at the time of inspection, the hazardous compounding for non-sterile products area does not have the number of air changes per hour documented on the certification reports. Please have the number of air changes per hours checked and send a copy to the Inspector.
5. CCR 1735.6(e)(2)	Compounding Facilities and Equipment. Hazardous drug compounding shall be completed in an externally vented exhausted physically separate room with the following requirements: Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and In that, at the time of inspection, the hazardous compounding for non-sterile products area does not have negative pressure of 0.01 to 0.03 inches of water column relative to all adfacent spaces. The room has positive pressure 0.01 " water column relative to all adjacent spaces today per the magnahelic gauge. ENV services documents positive pressure of 0.363 on 4/7/2022. Please get the air pressure direction fixed and send certification report to Inspector showing the room has negative pressure with the correct pressure range.
6. BPC 4076.7	Caution Label Required for Drug Containing an Opioid. In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction." In that, at the time of inspection, the pharmacy dispenses opioids for animals and does not have the opioid caution auxiliary sticker stating there is a risk of over dose and addiction.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____

Inspector (print) Denise Dodd

Date 2/2/2023

Signed _____

Print Name Erik Clausen

Title General Manager + PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

Erik Clausen <erik.clausen@bravacare.com>

To: Nasro Ali <nasro.ali@bluerabbit.vet>

See below for correspondence with the BOP to resolve the corrections.

Erik Clausen, PharmD/MBA
General Manager & Corporate Pharmacist-In-Charge

phone: **(415) 455-5590**
email: **erik.clausen@bravacare.com**
website: **bravacare.com**

a

brava

We're excited to introduce our new name! More updates are coming soon as we build an even better experience for veterinarians, clients, and the pets we all love.

CONFIDENTIALITY NOTICE

This transmission including any attachments may contain Protected Health Information (PHI). Therefore this transmission is HIGHLY CONFIDENTIAL and PRIVILEGED. It is to be used only to aid in providing specific healthcare and/or related services to the patient(s). Any other use is a violation of Federal Law (HIPAA) and will be reported as such. If you have received this transmission in error, please notify the sender immediately. Any use, dissemination, distribution or copying of the information contained within or attached is strictly prohibited. Please destroy all electronic and hard copies of the communication, including any and all attachments.

From: Dukatz, Denise@DCA <Denise.Dukatz@dca.ca.gov>
Sent: Wednesday, February 15, 2023 8:34 AM
To: Erik Clausen <erik.clausen@bravacare.com>
Subject: RE: Corrections

Dear Erik Clausen,

Thank you for sending the remedial actions for the corrections issued during an inspection on 2/2/2023. They have been received and accepted. This concludes this inspection.

Kind Regards,

Denise Dukatz

California State Board of Pharmacy
(415)629-9319 | FAX (415)242-6219 | **denise.dukatz@dca.ca.gov**

WARNING:

erik.clausen@bravacare.com

Hi Denise,

Please find attached the following documents:

1. CCR 1735.3(a) - a sample worksheet for Methimazole showing manufacturer information for the methimazole lot in question. We identified that the lot number for the methimazole that was missing from the manufacturer was due to that lot number coming over incorrectly during the data transition from our old software to the new software. We re-added the lot number under the correct manufacturer so it will be accurate moving forward. For our anhydrous suspension base, we added "manf in house" to the title to meet the requirement. See the attached master formula. We have not yet used a new batch, so it is still printing without the manufacturer, but all future batches should indicate that in the title. In the meantime, we are putting it in the notes (see methimazole sample formula). We also notified staff that if they see a similar situation moving forward with any other products, to a) notify management so we can rectify and b) notate the manufacturer in the notes until the problem is resolved.
2. CCR 1735.4(a)(5) - a sample label showing the "date compounded" on the label. This was actually something that the software was doing, but the date compounded was cut off on the sample label provided to you that day.
3. CCR 1735.4(a)(3) - a sample label showing the room temperature storage requirement added to the label. All room temperature formulations are currently being updated to reflect this requirement.
4. CCR 1735.6(e)(1) - an updated certification report showing negative pressure and air changes per hour in the USP 800 Hazardous Lab
5. CCR 1735.6(e)(2) - an updated certification report showing negative pressure and air changes per hour in the USP 800 Hazardous Lab as well as previous documentation showing that the HVAC units were being serviced at the time of the inspection resulting in the positive pressure at that time.
6. BPC 4076.7 - A sample of the opioid auxiliary label in use since the inspection

Please let me know if there is anything else that you should need from me. Thank you very much for your time and guidance.

Regards,

Erik Clausen

Erik Clausen, PharmD/MBA
General Manager & Corporate Pharmacist-In-Charge

phone: (415) 455-5590
email: erik.clausen@bravacare.com
website: bravacare.com



We're excited to introduce our new name! More updates are coming soon as we build an even better experience for veterinarians, clients, and the pets we all love.

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Methimazole 25mg/ml Suspension [27621]

Date compounded: 2023-02-14 14:56

Lot #: 550181

15c11764-a631-4c06-9648-977718927451

Formula Type: Anhydrous Suspension
Estimated Time:
Location: Not Set
Formula stability span: 180 days
Hazardous
Quantity: 32
Beyond Use: 2023-08-01
Task Performed By: Janine German, Brenda Luke
Verified By: Brenda Luke
Station:
Preparation Environment: Specific Pressure Environment Not Required/Not Used
Route of Administration: Oral route

Ingredients

✔ METHIMAZOLE USP 53843 — **0.800gm**

☑ Checked By: Brenda Luke [2023-02-14 3:29:13 pm]

Lots:

2203160080 [LETCO MEDICAL - 62991151505]
Beyond Use: 2023-11-16
Quantity Used: 0.799

Measurements Log
0 [jgerman - 2023-02-14 2:58:24 pm]
~~0.798~~ [jgerman - 2023-02-14 3:00:04 pm]
0.799 [jgerman - 2023-02-14 3:00:11 pm]
0 [jgerman - 2023-02-14 3:00:26 pm]

✔ Anhydrous Suspending Vehicle 53491 — **QS to 32.000mL**

☑ Checked By: Brenda Luke [2023-02-14 3:29:14 pm]

Lots:

542438
Beyond Use: 2023-08-01
Quantity Used: 32.000

Measurements Log
32 [jgerman - 2023-02-14 3:00:33 pm]

✔ VETERINARY FLAVORING (OIL) 12391 — **0.320 / 0.320mL**

Lots:

2208040192 [LETCO MEDICAL - 62991315902]
Beyond Use: 2023-09-28
Quantity Used: 0.320

Measurements Log
0.32 [jgerman - 2023-02-14 3:00:56 pm]

Total Weight: 0.799

Equipment Used:

Equipment Name	User
Scale Quintix 09	jgerman 2023-02-14 2:57 pm

Instructions

EQUIPMENT NEEDED: POWDER CONTAINMENT HOOD, ANALYTICAL BALANCE, WEIGH BOATS, SPATULAS FOR WEIGHING, MORTAR AND PESTLE OR OTHER SUITABLE MIXING DEVICE, SYRINGE OR OTHER SUITABLE MEASURING DEVICE FOR LIQUIDS, AMBER VIAL FOR DISPENSING

1. WEIGH OUT POWDER INGREDIENTS AND RECORD WEIGHT
If using tablets, place the appropriate number of tablets in a mortar, pulverize, then triturate to a fine, uniform powder. If using capsules, open each capsule and empty entire contents into mortar. Then triturate to a fine, uniform powder. If using commercial solution, measure out appropriate amount.
2. WET POWDER (OR MIX LIQUID INGREDIENTS) WITH ANHYDROUS SUSPENDING VEHICLE AND MIX INTO A

SMOOTH PASTE, THEN QS TO FINAL VOLUME WITH REMAINING ANHYDROUS SUSPENDING VEHICLE AND MIX WELL TO ENSURE ALL INGREDIENTS ARE INCORPORATED. MIXING TIME: ~1-2 MINUTES.
3. ADD OIL MISCIBLE FLAVOR AND MIX WELL TO INCORPORATE FLAVOR. MIXING TIME: ~1-2 MINUTES
4. SHAKE WELL, DISPENSE IN AN AMBER VIAL, STORE AT ROOM TEMPERATURE

Tasks

☑ Record Weight of Active Ingredients [Janine German]

☐ Record Weights of Inactive Ingredients if Applicable [⚠Incomplete]

☑ Document Volume of Liquid Ingredients [Janine German]

Documents

☑ Description of Final Product with Photo [Janine German]

Documents

Category:

Name	Note Preview
■	

Final Appearance: MILKY WHITE/CLOUDY SUSPENSION. FLAVORING MAY DARKEN AND ADD DISTINCTIVE SCENT.
Packaging: USP GRADE, TIGHT, WELL-CLOSED, LIGHT RESISTANT CONTAINER
Storage Instructions: ROOM TEMPERATURE

Packaging:	Storage Instructions:	Final Appearance:
USP GRADE, TIGHT, WELL-CLOSED, LIGHT RESISTANT CONTAINER	ROOM TEMPERATURE	MILKY WHITE/CLOUDY SUSPENSION. FLAVORING MAY DARKEN AND ADD DISTINCTIVE SCENT.

Final Yield: 30 mL **Containers: 1** Note: Anydrous Base Manf In House

Anhydrous Suspending Vehicle (Manf: Brava CA LLC) [53491] active

Formula Name
Anhydrous Suspending Vehicle (Manf: Brava CA LLC)

Formula ID
53491

NDC
99000854972

☑ Add as ingredient?

Formula Type
Special Instruction Formula

Dosage Form
Suspension

Route of Administration
Oral route

☐ Sterile

Therapy Class
Other

Task Points
0

Required Time

Location

Stability Span
180

Status: active
Verified: 2023-02-09 by Erik Clausen [2]
Last Modified: 2023-02-09 by Erik Clausen

Auxiliary Labels

Shake Well

Ingredients

Description	Require Measurement Check Quantity Sufficient	Quantity
MCT OIL Code: 53779	☑ Check ☐ QS	40 mL
GLYCERYL MONOSTEARATE Code: 53672	☑ Check ☐ QS	1.1 gm
STEVIA EXTRACT 90% Code: 52878	☑ Check ☐ QS	0.08 gm

Total Weight

Quantity: 40

Instructions

Tasks

- WEIGH OUT GLYCERYL MONOSTERATE AND STEVIA AND RECORD WEIGHTS
- INCLUDE DOCUMENTATION OF LIQUID INGREDIENT VOLUME
- DESCRIPTION OF FINAL PRODUCT

› Details

Stability Supporting Documentation

USP 795 FOR NON-AQUEOUS LIQUID PREPARATIONS

Chemical Compatibility

Packaging

Storage Instructions

STORE AT ROOM TEMPERATURE

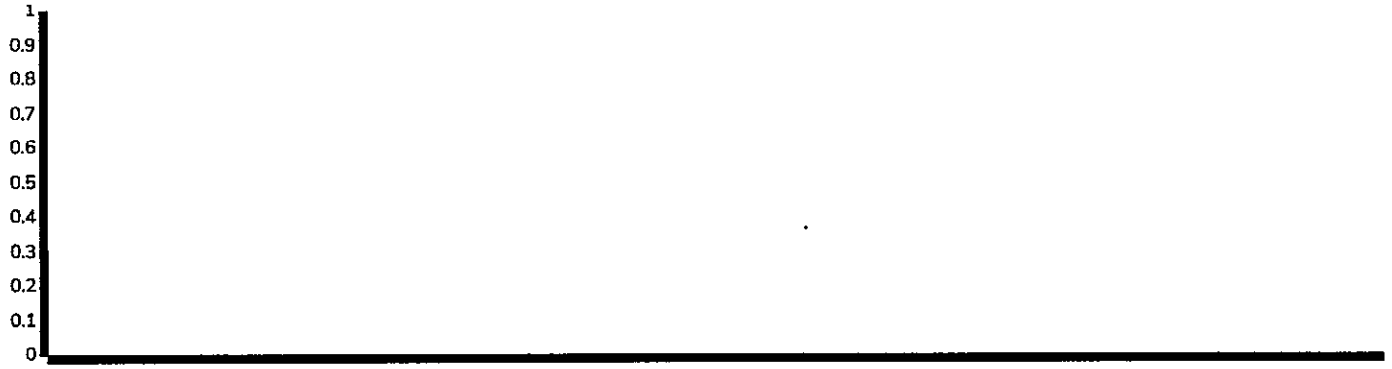
Final Appearance

MILKY WHITE/CLOUDY

SOP/Reference Documentation

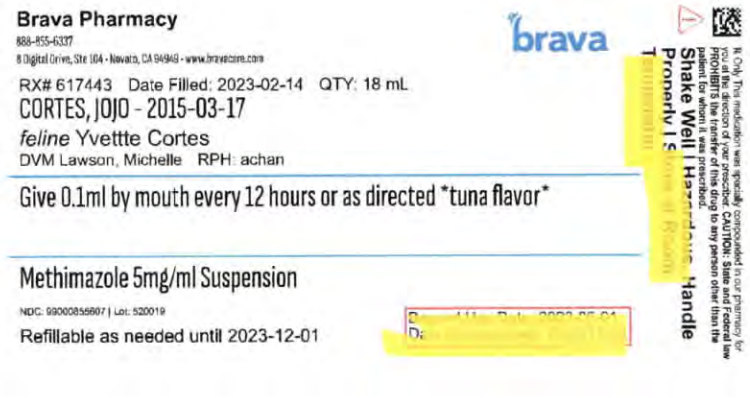
Documents

Anticipatory Compounding Limit: N/A - Download



History

Date	User	Note
2022-09-08 4 pm	ElectricLab	conversion
2022-09-24 9 pm	Vigil Rapiz	not all caps now
2023-02-09 5 pm	Erik Clausen	update name
2023-02-09 5 pm	Erik Clausen [2]	Formula re-activated



Brava Pharmacy
888-855-6337
8 Digital Drive, Ste 104 • Novato, CA 94949 • www.bravacare.com

brava

RX# 617443 Date Filled: 2023-02-14 QTY: 18 mL
CORTES, JOJO - 2015-03-17
feline Yvettte Cortes
DVM Lawson, Michelle RPH: achan

Give 0.1ml by mouth every 12 hours or as directed *tuna flavor*

Methimazole 5mg/ml Suspension

NDC: 99000856607 | Lot: 520019

Refillable as needed until 2023-12-01

Shake Well | Hazardous | Handle

Rx Only. This medication was specially compounded in our pharmacy for your pet. It is a violation of law to prescribe. CAUTION: State and federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Certification Report

Control ID #: 6008-294292-49779

Prepared for:

GOLDEN GATE VETERINARY
8 DIGITAL DRIVE, SUITE 104
NOVATO, CA 94949

Location Tested:
NEGATIVE PRESSURE RM

Date(s) Tested:
07 FEB 2023
Field Service Technician(s):
SHAWN DONALDSON

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C-SCA AIR EXHAUST VOLUMES & AIR CHANGES PER HOUR 6
TEST EQUIPMENT 7

SUMMARY REPORT

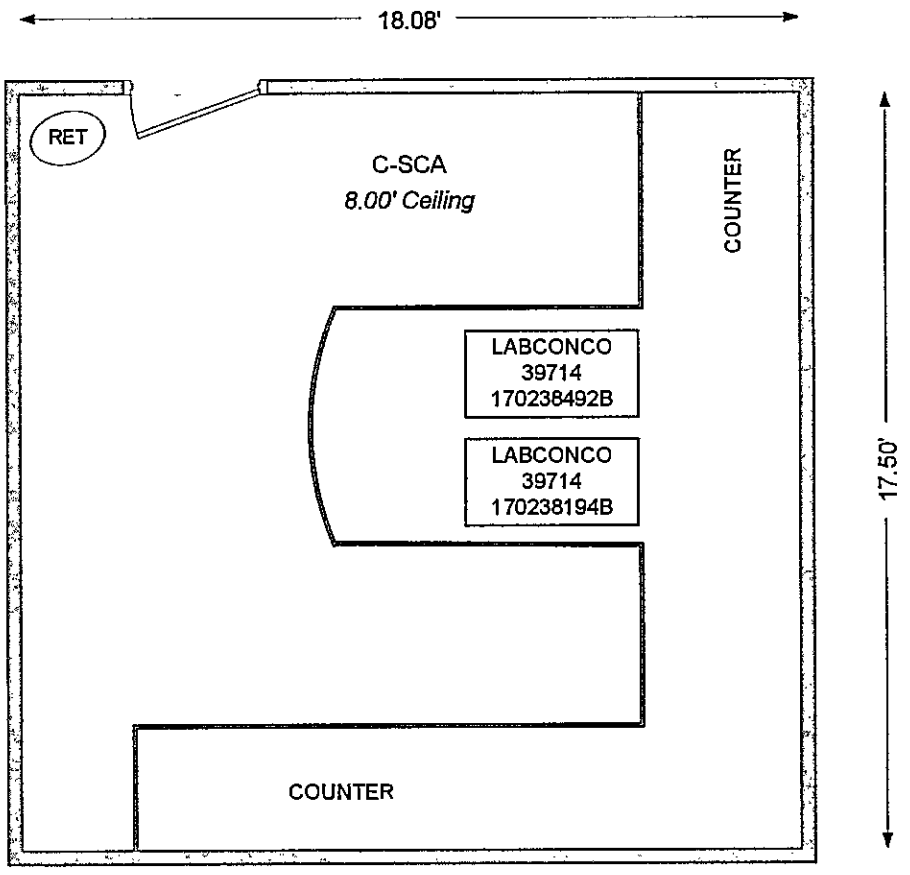
NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949

All testing is performed by qualified personnel using instrumentation, procedures, and methods which ensure measurements observed are reliable. All Testing is performed in accordance with current versions of ISO-17025, ISO-14644, USP<797>, <USP800>, <USP825>, and ENV's Quality Manual. Specifications comply with applicable IEST recommended practices, Current versions of CETA CAG-003-2006-13 for Sterile Compounding Facilities, CETA CAG-009 Viable Environmental Monitoring for Sterile Compounding Facilities, and/or customer determined specifications when applicable. Measurement instruments used are traceable to The National Institute of Standards and Technology (NIST). Results obtained apply to the specific room or equipment and are reflective of conditions at the time of this test.

ROOM PRESSURIZATION				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
C-SCA TO AMBIENT:	Negative | 0.028	Negative | 0.010 - 0.030	PASS	
C-SCA				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
Total Air Changes / Hr.	20	≥ 12	PASS	

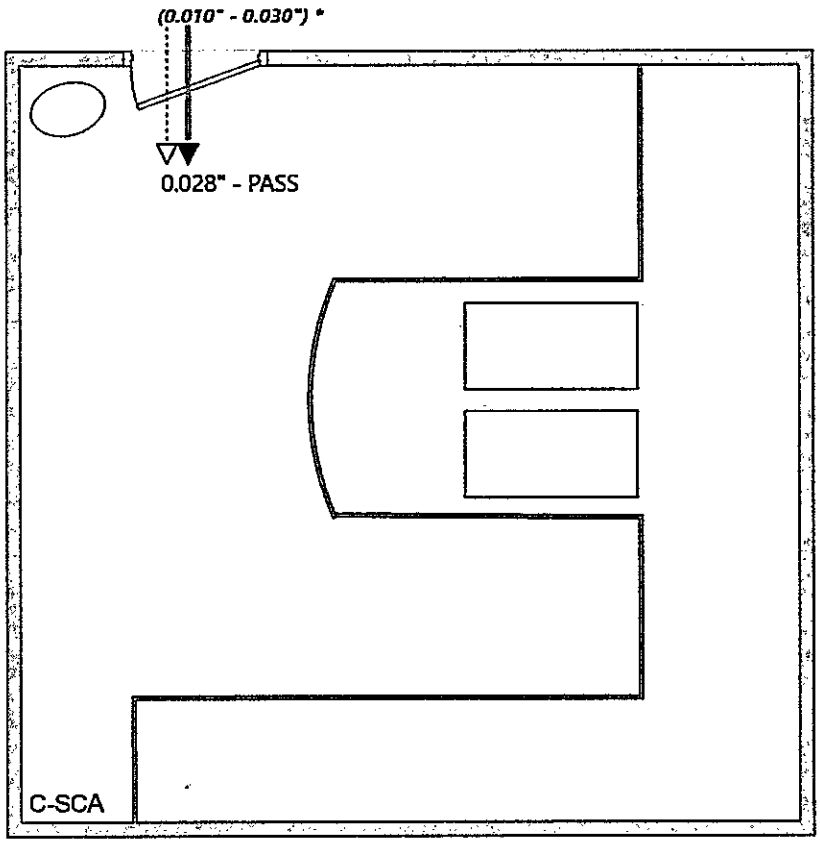
OVERVIEW

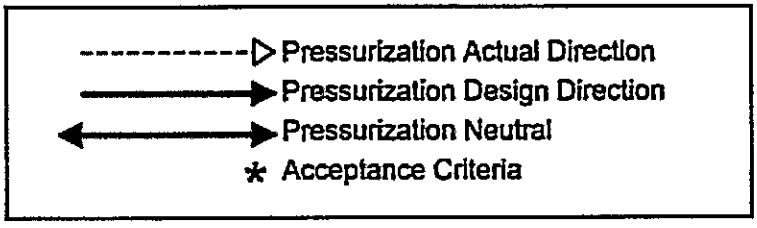
NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949



ROOM PRESSURIZATION

NEGATIVE PRESSURE RM
(UNITS IN INCHES WATER GAUGE) - OPERATIONAL / DYNAMIC
ROOM PRESSURIZATION

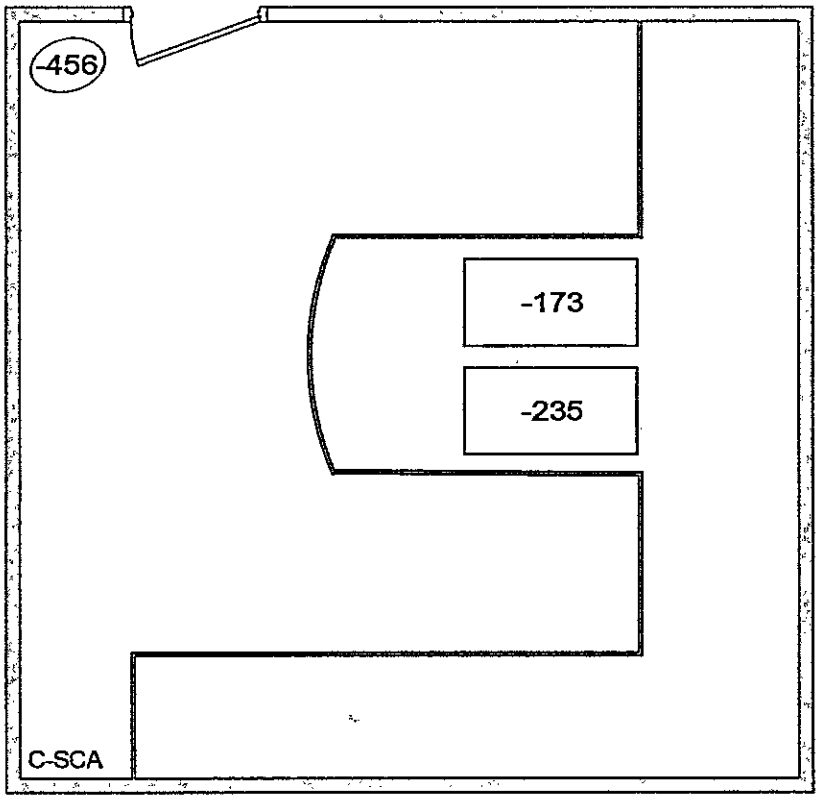




Test Result
PASS

AIR EXHAUST VOLUMES & AIR CHANGES PER HOUR

NEGATIVE PRESSURE RM
(UNITS IN CUBIC FEET PER MINUTE) - OPERATIONAL / DYNAMIC
C-SCA



2531	**Room Volume**
3	**No. of Readings**
864	**Total Air Exhaust Volume**
20	**Room Air Changes/Hour**
12	**Room ACH Specification**

Test Result
PASS

TEST EQUIPMENT

NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
ELECT. BALANCING TOOL	ALNOR	EBT721	90810046	30 JUN 23

Test equipment calibration certificates available upon request.
Company ID: CA0156-001 Unique ID: 621522

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59478

NAME: WEDGEWOOD PHARMACY LLC

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

8 DIGITAL DR #104
NOVATO CA 94949
MARIN COUNTY

ISSUANCE DATE

APRIL 30, 2024

EXPIRATION DATE

APRIL 1, 2025

CURRENT DATE / TIME

DECEMBER 30, 2024
3:25:35 PM

LICENSE RELATIONSHIPS

NAME: PETTICREW, TRISHA RENEE

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 77807 **PRIMARY STATUS:** CLEAR

Corporate Information
Wedgewood Pharmacy LLC
Wedgewood Connect LLC

Officers:

President:	Joseph Costa
CFO & Treasurer	Maria Kraus
Secretary	Marcy Bliss

Parent Companies:

Wedgewood Holdings Inc. (100% owner of Wedgewood Pharmacy LLC)
Specialty Pharma III Inc. (100% owner of Wedgewood Holdco Inc)
Specialty Pharma II Inc. (100% owner of Specialty Pharma III Inc.)
Specialty Pharma I Inc. (100% owner of Specialty Pharma II Inc.)
Specialty Pharma Holdings LP (100% owner of Specialty Pharma I Inc.)

Address:

405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Officers:

President & COO:	Joseph Costa
CFO:	Maria Kraus
CEO & Sec.:	Marcy Bliss

Directors:

Marcy Bliss
Sofia Gerard
Dennis Maloney
Kevin Vasquez
David Kamenetzky
Peter Berweger

Shareholders:

There are no individual shareholders in Wedgewood Connect/Village Pharmacy as both entities are member managed limited liability companies.

All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.

Marcy Bliss, Maria Kraus and Joseph Costa have served as officers at the following pharmacy locations:

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
7631 E. Indian School Road, Suite 105
Scottsdale, AZ 85251

ZooPharm LLC (now closed)
3131 Grand Ave., Unit C, Laramie, WY 82070

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Wedgewood Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): PH04110 (Brava Care LLC)

Physical Address: 8 Digital Dr STE 104

City: Novato State: CA Zip: 94954

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 415-455-5590 Website: bravacare.com

Licensing Company Email: brvlicensing@bluerabbit.vet

Section 2: Personal Information

First: Trisha Middle: Renee Last: Petticrew

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: CA Zip: 94954

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Texas at Austin		01/11-05/17	
Address	**City**	**State**	**Zip**
2515 Speedway	Austin	TX	78712
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Austin Community College		01/10-01/11	
Address	**City**	**State**	**Zip**
1212 Rio Grande St	Austin	TX	78701
Diploma/Degree obtained, if any			
Transferred to UT			

School Name		From - To (MM/YY – MM/YY)	
William B Travis High School		08/06-12/09	
Address	**City**	**State**	**Zip**
11111 Harlem Rd	Richmond	TX	77406
Diploma/Degree obtained, if any			
Highschool Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19-present	[redacted]	[redacted]	CA	94954
08/17-07/19			CA	94954
08/13-08/17			TX	78703
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Brava CA LLC (FKA Golden Gate Veterinary Compounding Pharmacy)			09/20-present
Business Address	**City**	**State**	**Zip**
8 Digital Dr STE 104	Novato	CA	94949
Phone	**Title**		**Number of Employed Hours**
415-455-5590	Pharmacist in Charge (PIC)		7440 hours
Description of Duties			
PIC from 11/23 - present; Staff pharmacist from 09/20-11/23 supervising technicians, compounding, dispensing, and providing consultation on prescriptions; record keeping			

Business Name			From - To (MM/YY – MM/YY)
Rite Aid Pharmacy			08/17-09-20
Business Address	**City**	**State**	**Zip**
218 N Main St	Sebastopol	CA	95472
Phone	**Title**		**Number of Employed Hours**
707-829-3007	Staff Pharmacist		6240 hours
Description of Duties			
supervising technicians, dispensing and consulting on prescriptions medications, record keeping			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

4/10/2024
Date

I, Trisha Petticrew, **certify that as the designated representative for**

Wedgewood Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. trp I am at least 21 years of age;
3. trp I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. trp I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. trp I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. trp I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. trp I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Trisha Petticrew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/9/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Trisha Petticrew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/9/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, Trisha Petticrew, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/9/2024

Date

Subscribed and Sworn to before me this 9th day of April.

Samantha Botnick

Notary Public Signature

Samantha L Botnick
NOTARY PUBLIC
State of New Jersey
ID # 50130085
My Commission Expires
June 25, 2025

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FG0344767	07-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-02-2021

BRAVA CA LLC
8 DIGITAL DR STE 104
NOVATO, CA 949495759

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FG0344767	07-31-2024	$888

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Form DEA-223 (9/2016)

wedgewood
PHARMACY

RECEIVED
4/17/24
Fee Processed

April 15, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno Nevada 89521

RE: Change of Ownership Brava CA LLC
License Number: PH04110

Dear Sir/Madam:

Enclosed please find an application for the change of ownership of Brava CA LLC ("Brava"). Brava is a compounding pharmacy located in Novato, California that compounds non-sterile medications for veterinary use.

As part of an internal reorganization to be completed on or about April 30, 2024, Brava will merge into Wedgewood Pharmacy LLC. Please note that Wedgewood Pharmacy LLC is the new name of Wedgewood Village Pharmacy LLC and the change of name is occurring concurrently with the internal reorganization. This aspect of the reorganization is a name change only as the FEIN and type of legal entity is not changing.

Wedgewood Pharmacy's parent companies will change to more streamline the company's organizational structure. These changes are all internal restructuring and no new external investments are being made into the company.

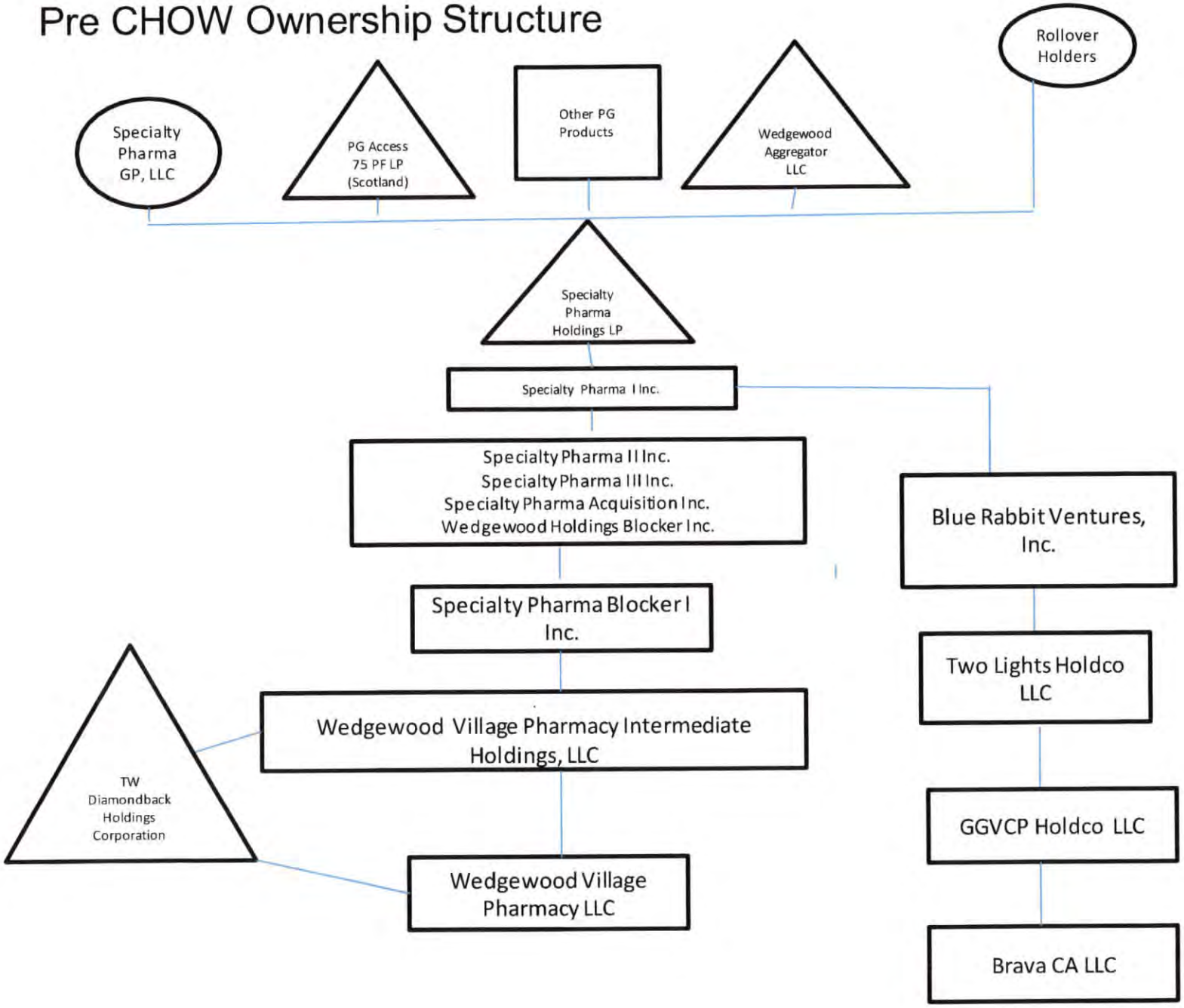
For your reference, we have enclosed before and after organization structure charts demonstrating the nature of the change as well as updated ownership information.

Should you have any questions or require additional information, please do not hesitate to contact me at (559) 361 - 2342 or rachel.taggs@precisionpharmacy.com.

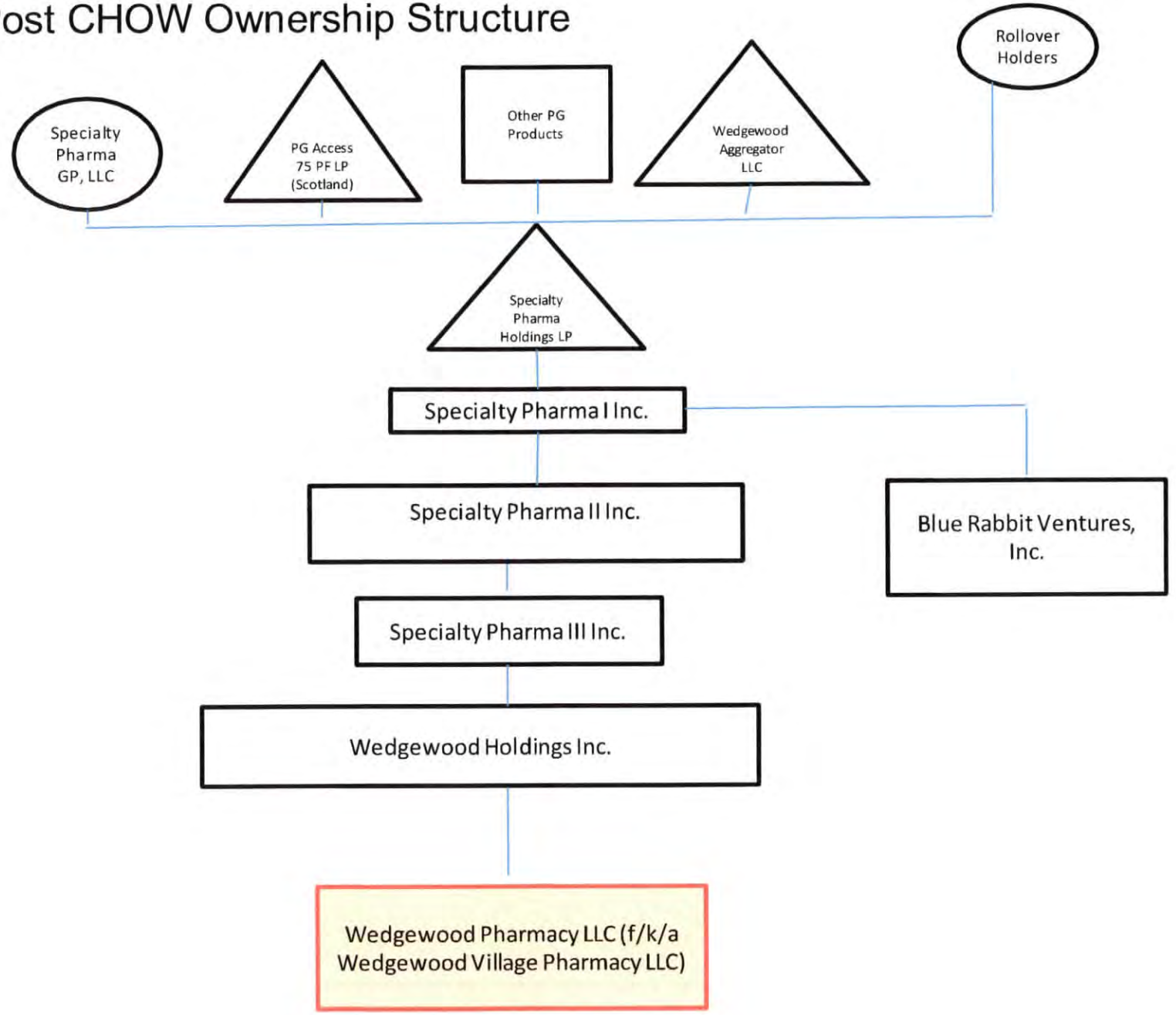
Sincerely,

Rachel Taggs
Sr. Compliance Specialist

Pre CHOW Ownership Structure



Post CHOW Ownership Structure



Section 3: History of Company

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Swedesboro, NJ Location

The list includes prior matters that have previously been reported to the Board in an effort to provide full transparency with the application.

03/19/2015 – MN/MI/AL Consent Orders

On March 19, 2015, Wedgewood entered into a consent order with the Minnesota Board of Pharmacy ("*Minnesota Consent Order*"). Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("*Michigan LARA*") and the Alabama Board of Pharmacy ("Alabama BOP") to resolve "sister state" actions that arose out of the Minnesota Consent Order.

The basis for the Minnesota Consent Order are as follows:

Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood from its NJ location, dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty but admitted no wrongdoing.

Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama Consent Order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibitions on sister state actions.

10/22/2015 – New Jersey Consent Agreement

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid to the Board is not considered a fine or other sanction.

10/13/2017 – California Citation & Fine

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

07/20/2018 - DEA Memorandum of Agreement

While Wedgewood does not consider there to be a restriction on its handling of CDS or disciplinary action, however, out of an abundance of caution, Wedgewood is disclosing the following:

As a condition of issuing Wedgewood located in Swedesboro, New Jersey a DEA manufacturer registration, Wedgewood and the DEA entered into a Memorandum of Agreement ("MOA") for a period of five years (until July 20, 2023) during which Wedgewood agreed not to use the DEA manufacturer license to manufacture or distribute controlled substances for human use. Wedgewood obtained a DEA manufacturer registration for the sole purposes of providing controlled substance compounds solely for veterinarians to use for office use.

12/5/2018 – California Citation

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds.

Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a Close Out letter on March 1, 2019. No penalty or fine was assessed.

6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

Rachel Taggs
Sr. Compliance Specialist
Wedgewood Pharmacy

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro: 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 1 9 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: **In the Matter of Wedgewood Pharmacy**
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Dunne Morris,

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY KLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112625	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0066

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the ____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112626	)	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0086

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(a) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____ _____, 2016 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2018 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2018 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goelz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullock, Esq., of Hansford Reneis and Rachael G. Fentiker, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedures:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

11. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified changes, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or omission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY BLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remele and Rachael C. Pontikes, Esq., of Dunn Morris.

EXHIBIT A page 1 of 7

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT 4 page 3 of 7

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

EXHIBIT A PAGE 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

EXHIBIT A page 5 of 7

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

EXHIBIT A page 6 of 7

CONSENT:

MARCY BLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly M. Riggard

Kelly K. Riggard (P45884)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2014

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/14

Alan T. Ruddell (P44660)
Attorney for Respondents
Dated: 3/31/2014

4

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Geedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Geedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Gaedeke, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-15-137239, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 58-01-008041

Complaint No. 58-15-137238

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 58-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division -- Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 3/31/2016

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. No. (973) 648-4730

FILED
OCT 22 2015
BOARD OF PHARMACY

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.:28RS00316800

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.

- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).

- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of $500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr., RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Ludmilla P Malmberg
Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and entry:

Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	**A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board**	**$1,000.00**

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: November 12, 2017

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☑ I contest the Citation and request an Office Conference.

Check One:

☑ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: Margy Ann Bliss

Signature: [redacted] Dated: 10/26/17

Address of Service: [redacted]

City: [redacted] State: NJ Zip: 08085

Telephone: (Business) (856) 832-1303 Residence: (609) 320-5050

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

[redacted]

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 23, 2017

Wedgewood Village Pharmacy
Attention: Alison Lynch
405 Heron Dr., Ste. 200
Swedesboro, NJ 08085

RE: Complaint Investigation CI 2016 72146

Dear Pharmacist-in-Charge:

The Board of Pharmacy has completed its investigation of Wedgewood Village Pharmacy.

As a regulatory agency, when conducting an investigation, the Board must adhere to violations prohibited in pharmacy law. Specifically, the information and documentation obtained during the course of an investigation must clearly demonstrate that a violation of pharmacy law occurred.

The Board's analysis of the information and documentation received did not identify sufficient evidence to determine that a violation of pharmacy law occurred. Accordingly, the Board is closing the matter and will be taking no action against the pharmacy or its licensees.

Although we are closing this matter, please be advised that it is your professional responsibility to assure compliance with all pharmacy laws.

We would like to thank you for your cooperation and assistance. If you should have any questions, please contact the Board at the above address or telephone number.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By

Tina Rojas
Complaint Unit Analyst

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY DIVISION
CAMDEN RESIDENT OFFICE

IN THE MATTER OF:

Wedgewood Village Pharmacy, LLC — DEA Application# W15007898E
Wedgewood Animal Wellness, LLC — DEA Application# W17088272E
405 Heron Drive
Swedesboro, NJ 08085

MEMORANDUM OF AGREEMENT

On or about 2/5/2015, the Drug Enforcement Administration (DEA) received an application for controlled substance registration (DEA control number W15007898E) from Wedgewood Village Pharmacy, LLC 405 Heron Drive, Swedesboro, NJ 08085. On or about 8/18/2017, DEA received another application for controlled substance registration (DEA control number W17088272E) from Wedgewood Animal Wellness LLC, 405 Heron Drive, Swedesboro, NJ 08085.

This Memorandum of Agreement (MOA) between the DEA and Wedgewood Village Pharmacy LLC establishes terms and conditions under which the DEA will issue a registration to Wedgewood Village Pharmacy LLC as a Manufacturer to handle Schedules III through V controlled substances subject to the terms set forth below in this Memorandum of Agreement. This MOA applies only to the manufacturing registration to be issued to Wedgewood Village Pharmacy LLC.

Wedgewood agrees to enter into this MOA with the DEA for a period of five (5) years from the date the MOA is signed and fully executed. The MOA shall be considered fully executed when all parties to the MOA have signed and dated the MOA.

Wedgewood agrees to not manufacture or distribute any controlled substances for human use under the DEA issued manufacturing registration.

Wedgewood agrees to contact DEA immediately if there is any change to their business practice of selling controlled substances for animal use only pursuant to their DEA issued manufacturing registration.

Wedgewood shall abide by and obey all federal, state, and local laws and requirements relating to controlled substances.

Wedgewood agrees to immediately notify DEA if there is any change of status in its State of New Jersey license and/or State Controlled Dangerous Substance license, including any actions filed against these licenses.

Wedgewood agrees to allow DEA to conduct onsite inspections, including inspections of its controlled substances records, without prior notice pursuant to a Notice of Inspection of Controlled Premises and without requiring DEA to obtain an Administrative Inspection Warrant, Search Warrant, or other means of entry

Wedgewood agrees that this MOA constitutes the entire agreement between Wedgewood and DEA, and may only be modified or amended by a subsequent document executed in the same manner by both parties in writing.

Wedgewood shall report any professional, civil, or criminal action concerning controlled substances that is pending or taken against the firm by any state, federal, or professional agency or governing body to DEA, Camden Resident Office.

Wedgewood shall maintain a complete and accurate record of all controlled substances manufactured or distributed pursuant to this manufacturing registration.

Wedgewood agrees by executing this MOA, it waives judicial review, and will not challenge or contest the validity of any terms or conditions of this agreement.

The parties further agree that should Wedgewood violate any terms or conditions of this agreement, such violation may constitute grounds for the revocation, or the revocation and immediate suspension, of Wedgewood's DEA manufacturing registration. Nothing in this MOA shall preclude Wedgewood from contesting any subsequent Order to Show Cause, or Order to Show Cause and Immediate Suspension, of its DEA manufacturing registration as permitted under the Controlled Substances Act and the Administrative Procedure Act. Nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any violations, past or subsequent, as grounds for revocation of Wedgewood's DEA manufacturing registration, either by themselves or in conjunction with other grounds, in the event that future DEA administrative proceedings become necessary. Furthermore, DEA is not precluded from introducing this MOA at any subsequent DEA administrative proceeding.

DEA agrees to promptly approve Wedgewood's application for a manufacturing registration, control# W15007898E, upon the signing of this MOA by both parties.

The parties agree that Wedgewood's application, control# W17088272E is withdrawn effective the execution of this agreement.

The responsible Wedgewood official below acknowledges and states that s/he has read the foregoing and understands and agrees with the contents herein and that s/he has signed this MOA.

The parties enter into this MOA with the understanding that the Drug Enforcement Administration and Wedgewood Village Pharmacy LLC will abide by its contents in good faith.

Wedgewood Village Pharmacy, LLC — Date: 7/20/18

FOR THE DRUG ENFORCEMENT ADMINISTRATION

Nancy Coffey
Diversion Program Manager
New Jersey Division — Date

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to fumishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT

Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2018 82132
NRP 1826

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2018 82132 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NRP 1826
CITATION AND FINE CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4678

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2016 73882
NSC 100970

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2016 73882 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NSC 100970
CITATION AND FINE CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4685

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**	**$2,500.00**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

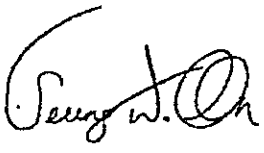
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:
By: MARCY ANN BLISS Marcy Ann Bliss
25DA168EA289425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:
Derek Shaffer
DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
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Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7286
WEDGEWOOD VILLAGE PHARMACY LLC; **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	**ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

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D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number CI 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number CI 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

///

3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04376	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: ecommerce pet pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Agropec Trading, LLC DBA Allivet

Physical Address: 9882 East 121st Street

City: Fishers State: Indiana Zip: 46037

Mailing Address (if different from physical address): 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Telephone: 305-999-5914 Toll Free # (NAC 639.708, NRS 639.23286): 877-500-9944

Fax: 877-500-9950 Contact Email: ani@allivet.com

Website: https://www.allivet.com/

Nevada Business License # (if applicable) NV20212250091

Supervising/Managing Pharmacist Name (NRS 639.220): Mitchell Alexander Manor

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Nevada 23309

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mitchell Alexander Manor (PIC)	NV Pharmacist Registration #: Nevada 23309
Name: Ryan R. Jenkinson	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Grandparent Entity - See attached corporate structure

Corporation Name: Tractor Supply Company

Mailing Address: 5401 Virginia Way

City: Brentwood State: TN Zip: 37027

Telephone: (615) 440-4000 Email: rmills@tractorsupply.com

Contact Person Name: Robert Mills

Date of SEC Registration: 02/17/1994 | SEC Registration Number: 000-23314 | Stock Exchange Symbol: TSCO

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Allivet, Inc.

Corporation/Organization Name: Agropec Trading, LLC dba Allivet

Mailing Address: 14540 NW 60th Avenue

City: Miami Lakes State: FL Zip: 33014

Telephone: 305-999-5914 Email: ani@allivet.com

Contact Person Name: Anabel Molinar

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the EVP, Officer (title) for Tractor Supply Company (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NR5 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert Dean Mills

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/6/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, John Jairo Navas hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Officer (title) for Agropec Trading, LLC DBA Allivet (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18th day of November, 2024

Notary Public

NOTARY PUBLIC
Expires
11/29/2025
Anabel Moliner
My Commission
HH 203043
STATE OF FLORIDA

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert D. Mills

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/5/24

Date

Board Use Only	Date Received: _____	Amount: 500.00 / VT# 34644

Allivet
Your Ally in Pet Pharmacy Care
www.allivet.com

November 13, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, Nevada 89521

Re: Agropec Trading, LLC dba Allivet

Nevada Pharmacy Application – Signed Statement of State Actions Explanation

This statement serves as an explanation in response to Section 3, Question 3: History of Company, on the Nevada Pharmacy application, which was answered "Yes."

Agropec Trading, LLC, doing business as Allivet, has been the subject of regulatory actions concerning its licenses in other states, specifically related to our Miami Lakes, Florida pharmacy.

A detailed summary of the state actions related to this matter is attached for your review.

I affirm that the above information and the attached documentation are true and correct to the best of my knowledge.

John Jairo Navas – Officer

Signature: _____

Date: 11/13/2024

Allivet
Your Ally in Pet Pharmacy Care

14540 NW 60th Ave
Miami Lakes, FL 33014
Phone 877-500-9944
Fax 877-500-9950
www.allivet.com

State Disciplinary Actions

1. **Oregon - 2008-0097 - 12/09/08**

   The case with the state of Oregon was opened on Dec 9th, 2008, and settled with a consent order dated February 18th, 2009. There was a civil fine of $750 due to Allivet shipping to Oregon in early 2008 without an out of state license. This was an unintentional oversight as Allivet was a new pharmacy and was in the process of obtaining all licenses.

2. **Indiana - 2011 IBP 0053 - 09/28/11**

   Allivet began shipping prescription orders into the state of Indiana while the pharmacy application was still in process. Because of that, Indiana sent a stop-ship order dated September 28th, 2011. Allivet received its out of state pharmacy license from the state of Indiana in December 2011 and was able to continue operating without any further issues.

3. **Alabama-16-L-0130 - 02/28/17**

   This action was a ***derivative action*** referencing the following disciplinary actions:

   - Oregon - 2008-0097 - 12/09/08
   - Indiana - 2011 IBP 0053 - 09/28/11

4. **Colorado - CO-2013-534 - 12/19/13**

   Allivet was fined $1,100 by Colorado for dispensing medications without a wholesale license to a veterinarian. At the time of the incident in 2011, Isoxsuprine was on manufacturer backorder, but Allivet had the product in stock. Due to the product's constrains Allivet was contacted by a veterinarian urgently requiring this medicine for his pet owners in Colorado. Allivet provided the medication, unaware of the wholesale licensing requirements. Allivet does not engage in any wholesale pharmacy transactions to ensure full compliance with state regulations.

5. **Alabama-AL-2015-001 - 10/10/15**

   Allivet applied for a Pharmacist-in-Charge (PIC) license with the Alabama Board of Pharmacy on November 10, 2014, to facilitate the renewal of its pharmacy license for 2015. Alabama scheduled a meeting for Allivet's pharmacist in February 2015, beyond the expiration date of the license on December 31, 2014. To address this, Allivet contacted the Board of Alabama to request an earlier meeting and to confirm that its renewal would not be affected by the schedule. During this time, it was assured that Allivet's pharmacy license would remain in good standing until the in-person meeting, and the Board's website indicated the license as active. Operating under this assumption, Allivet continued shipping products. When questioned about early 2015 shipments, Allivet explained that it believed it was permitted to do so based on prior communications. As a result, Allivet was fined $500 for shipping into the state without an Alabama-licensed Pharmacist-in-Charge.

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6. **Arkansas-AR-2015-049 - 10/13/15**

   In 2015, a technical issue in Allivet's system compromised the designated safety measures to prevent shipment of prescription items without active licenses. As a result, orders placed over the phone were processed and shipped into Arkansas without a valid license in 2015.

7. **Alabama-17-L-0050 - 05/18/17**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

8. **Colorado - 2018-6062 - 08/13/18**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

9. **Michigan-53-17-148216 - 06/25/18**

   Action I:
   In late 2008, Allivet changed locations and failed to report the change of location within 30 days to the Michigan Board of Pharmacy. This was an unintentional oversight as Allivet had just opened its pharmacy in 2007. At the following renewal date, Allivet noted the new address which triggered the action.

   Action II:
   This action was a ***derivative action*** referencing the following disciplinary actions:
   - Oregon - 2008-0097 - 12/09/08
   - Alabama-AL-2015-001 - 10/10/15
   - Arkansas-AR-2015-049 - 10/13/15

10. **Texas-K-17-031 - 07/09/18**

    Action I:
    This action was a ***derivative action*** referencing the following disciplinary actions:

    - Oregon - 2008-0097 - 12/09/08
    - Indiana - 2011 IBP 0053 - 09/28/11
    - Colorado - CO-2013-534 - 12/19/13

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Action II:
On September 1st, 2016, the Texas Board of Pharmacy changed the requirement for non-resident pharmacies to have a licensed Texas Pharmacist in Charge. Allivet immediately began the process to obtain licensure for its pharmacist, but due to the lengthy process, the license was not granted until May 2017. Therefore, due to the Texas regulatory change, Allivet operated without a Texas-licensed Pharmacist-in-Charge from September 1, 2016, to May 21, 2017. Currently, Allivet holds an active license and is in good standing with the state of Texas.

11. Illinois - 021930788 - 11/05/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Oregon - 2008-0097 - 12/09/08
- Indiana - 2011 IBP 0053 - 09/28/11
- Colorado - CO-2013-534 - 12/19/13
- Alabama-AL-2015-001 - 10/10/15
- Arkansas- AR-205-049 - 10/13/15
- Michigan-53-17-1481216 - 06/25/18
- Texas-K-17-031 - 07/09/18

12. Hawaii-RICO Case No. PHA 2019-79-L - 12/26/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Texas-K-17-031 - 07/09/18
- Michigan-53-17-148216 - 06/25/18

13. Alabama-19-L-0007 - 01/06/20

This action was a ***derivative action*** referencing the following disciplinary actions:

- Florida Case No. 2008-26608[1]
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Michigan-53-17-148216 - 06/25/18
- Alabama-16-L-0130 - 02/28/17
- Alabama-17-L-0050 - 05/18/17

[1] Original case was under a different pharmacy license, which has no impact or connection to Allivet's current license nor disciplinary history.

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14. Hawaii-RICO Case No. PHA 2020-168-L - 01/18/21

This action was a ***derivative action*** referencing the following disciplinary actions:

- Michigan-53-17-148216 - 06/25/18
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Illinois- 021930788 - 11/05/19

15. Nebraska - Censure Complaint #20190354 - 07/09/20

This censure derived from selling rabies vaccines to consumers in Nebraska, instead of the prescribing veterinarian. Allivet has since taken down the sales of all rabies vaccines across all 50 states to avoid similar circumstances where the Board changes its stance with this product. Dismissal order matter was approved by Hearing Officer on 07/09/2020.

16. Alabama - Consent Letter - 11/10/21

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20

17. Hawaii - RICO Case No. PHA2022-2-L - 05/25/22

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20
- Alabama - Consent Letter - 11/10/21

Non-Disciplinary Communications

1. Tennessee – Consent Letter – 01/25/2024 Case No. 2023026981

In June 2023, the company changed the Pharmacist in Charge (PIC) at its Miami facility and as required, notified each State Board of Pharmacy. Unfortunately, the notification sent to Tennessee contained an incorrect date, suggesting that there was a brief period when the Miami facility did not have a PIC. This was merely a clerical error. The company has provided all requested records to the Tennessee Board, along with an affidavit from the PIC, demonstrating compliance with PIC regulations at all times. On October 16, 2024, the Tennessee Attorney General for the Board of Pharmacy communicated that the case was closed. No discipline was imposed.

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Miami Lakes, FL 33014
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Fax 877-500-9950
www.allivet.com

2. **Missouri – Letter of Concern – 03/28/2024**

This action was a letter of concern related to the failure to report disciplinary action taken by Hawaii (RICO Case No. PHA2022-2-L; see 17 above). No discipline was imposed.

State of Florida
Department of State

I certify from the records of this office that AGROPEC TRADING, LLC is a limited liability company organized under the laws of the State of Florida, filed on February 22, 2017, effective December 9, 1993.

The document number of this limited liability company is L17000041105.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on January 4, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourth day of January, 2024

Secretary of State

Tracking Number: 6812209961CC

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Delaware

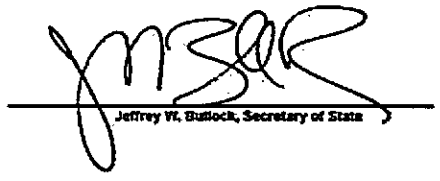
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TRACTOR SUPPLY COMPANY" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





949106 8300

SR# 20244239362

Authentication: 204897649

Date: 11-18-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
Allivet
9882 E 121st Street
Fishers IN 46037
Phone: 8775009944
Owner:
Ownership Type:

LICENSE
License No: 60006794A
Profession: Pharmacy
License Type: Pharmacy
9882 E 121st Street
Fishers IN 46037
Phone: 8775009944

Inspection Type:	Pharmacy Inspection
Inspection Date:	7/5/2023
Result:	Pass

Remarks: 16000 weekly. Only hirer licensed techs. Filling and final product check only, no order entry. No controsl, no compounding. Plumbs resource on line.

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding
Remote Locations (Type II only)

Emergency Drug Kits/Crash Carts
Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.



Signature of Inspector

7/5/2023 3:12:20 PM

Date/Time



Signature of Owner/Representative

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

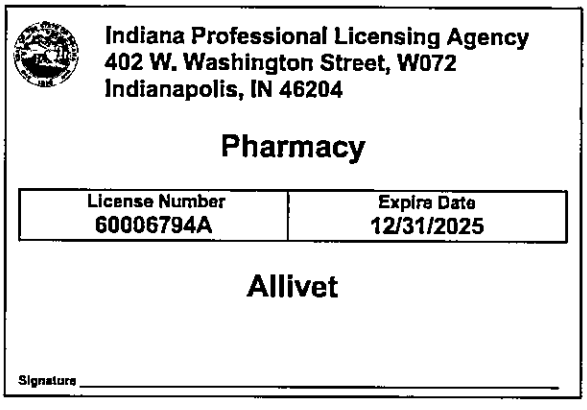
Pharmacy

License Number	Expire Date
60006794A	12/31/2025

Allivet

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency



STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information

Facility Name:	Allivet
Address:	9882 E 121st Street Fishers, IN 46037
Owner Name:	

License Information

Number Issued:	60006794A
License Type:	Pharmacy - Closed Door (III)
Status:	Active
Issue date:	11/12/2020
Expiration Date:	12/31/2025
Obtained By:	Application

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at https://www.in.gov/pla/license/free-search-and-verify/. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at https://www.in.gov/pla/professions/.

Digitally Certified on: Thu Oct 17 03:21:04 PM EST 2024

LIST OF OFFICERS

CURRENT OFFICERS

Allivet, Inc.
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

Agropec Trading, LLC
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

POST-CLOSE OFFICERS[1]

Tractor Supply Company[2]
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Seth Estep-Executive Vice President-Chief Merchandising Officer

Allivet, Inc.
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

Agropec Trading, LLC
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

[1] Note that the list of officers for Allivet, Inc. and Agropec Trading, LLC is a comprehensive list. However, the list of officers for Tractor Supply is an abbreviated list.
[2] A comprehensive list of officers of Tractor Supply's can be found on the Investor Relations webpage at: https://ir.tractorsupply.com/investor-relations/governance/executive-management/default.aspx

List of Top four Stockholders and their percentage of Ownership:

Agropec Trading LLC dba Allivet
Allivet, Inc. – 100%

Allivet, Inc.
Tractor Supply Company – 100%

Tractor Supply Company
Vanguard Group - 11.86%
Black Rock, Inc. – 8.93%
Capital international Investors – 6.09%
Capital World Investors – 5.42%

Corporate Structure



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Agropec Trading, LLC dba Allivet

Pharmacy/Wholesaler License # (if applicable): Pharmacy Nevada License # PH04376

Physical Address: 9882 East 121st Street

City: Fishers State: Indiana Zip: 46037

Mailing Address (if different from physical address): 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Telephone: 877-500-9944 Website: www.allivet.com

Licensing Company Email: compliance@allivet.com

Section 2: Personal Information

First: Mitchell Middle: Alexander Last: Manor

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City: Carmel State: IN Zip: 46032

Telephon[redacted] Email[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Ohio State University		5-09 to 5-13	
Address	**City**	**State**	**Zip**
217 Lloyd M Parks Hall	Columbus	OH	43210
Diploma/Degree obtained, if any			
Pharm. D			

School Name		From - To (MM/YY – MM/YY)	
Miami Ohio University		8-5 to 5-09	
Address	**City**	**State**	**Zip**
501 E. High St	Oxford	OH	45056
Diploma/Degree obtained, if any			
B.A. Zoology			

School Name		From - To (MM/YY – MM/YY)	
Anderson High School		8-01 to 6-05	
Address	**City**	**State**	**Zip**
7560 Forest Rd	Cincinnati	OH	45255
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8-23 to present	[redacted]	Carmel	IN	46032
7-17 to 8-23	[redacted]	Indianapolis	IN	46220
8-14 to 7-17	[redacted]	Knoxville	TN	37917
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alliet Pet Pharmacy			9-20 to present	
Business Address		**City**	**State**	**Zip**
9882 E 121st street		Fishers	IN	46037
Phone	**Title**		**Number of Employed Hours**	
18775009944	PIC		8320	
Description of Duties				
verify medication prior to dispensing, lead CQI meetings, maintain compliance with various state requirements.				

Business Name			From - To (MM/YY – MM/YY)	
Kroger Pharmacy			7-17 to 3-20	
Business Address		**City**	**State**	**Zip**
4445 E 10th st		Indianapolis	IN	46201
Phone	**Title**		**Number of Employed Hours**	
317-359-1638	PIC		6240	
Description of Duties				
counsel patients, administer vaccines, maintain state compliance, inventory, compound medications.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Mitcell Manor, **certify that as the designated representative for**

Allivet Pet Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MM I am at least 21 years of age;
3. MM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mitchell Manor

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-19-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Maer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-19-24

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, Mitchell Maer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-19-24

Date

Subscribed and Sworn to before me this 19th day of November, 2024

Karie M Cook

Notary Public Signature

KARIE MARIE COOK
Notary Public, State of Indiana
Marion County
Commission Number NP0755440
My Commission Expires
March 24, 2032

(Seal)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 02568	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: ecommerce pet pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Agropec Trading, LLC DBA Allivet

Physical Address: 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Mailing Address (if different from physical address): 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Telephone: 305-999-5914 Toll Free # (NAC 639.708, NRS 639.23286): 877-500-9944

Fax: 877-500-9950 Contact Email: ani@allivet.com

Website: https://www.allivet.com/

Nevada Business License # (if applicable) NV20212250091

Supervising/Managing Pharmacist Name (NRS 639.220): Runglak Kitiyasavatdi

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Nevada 21816

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Runglak Kitiyasavatdi (PIC)	NV Pharmacist Registration #: Nevada 21816
Name: Lee A. Hochmuth	NV Pharmacist Registration #: N/A
Name: Stephanie Tallerie	NV Pharmacist Registration #: Nevada 20790
Name: Cynthia Lomasky	NV Pharmacist Registration #: Nevada 20780
Name: Lenard N. Shaw	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Grandparent Entity - See attached corporate structure

Corporation Name: Tractor Supply Company

Mailing Address: 5401 Virginia Way

City: Brentwood State: TN Zip: 37027

Telephone: (615) 440-4000 Email: rmills@tractorsupply.com

Contact Person Name: Robert Mills

Date of SEC Registration: 02/17/1994 | SEC Registration Number: 000-23314 | Stock Exchange Symbol: TSCO

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Allivet, Inc.

Corporation/Organization Name: Agropec Trading, LLC dba Allivet

Mailing Address: 14540 NW 60th Avenue

City: Miami Lakes State: FL Zip: 33014

Telephone: 305-999-5914 Email: ani@allivet.com

Contact Person Name: Anabel Molinar

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the EVP, Officer (title) for Tractor Supply Company (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert Dean Mills

Print Name of Authorized Person

Robert Dean Mills

Original signature of Authorized Person (copies or stamps not accepted)

11/6/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, John Jairo Navas hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Officer (title) for Agropec Trading, LLC DBA Allivet (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18TH day of November, 2024

Notary Public

NOTARY PUBLIC
Expires
11/29/2025
Anabel Moliner
My Commission
HH 203043
STATE OF FLORIDA

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Mills

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/8/2024

Date

Board Use Only	Date Received: _____	Amount: 500.00 #34644

Allivet
www.allivet.com

November 13, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, Nevada 89521

Re: Agropec Trading, LLC dba Allivet

Nevada Pharmacy Application – Signed Statement of State Actions Explanation

This statement serves as an explanation in response to Section 3, Question 3: History of Company, on the Nevada Pharmacy application, which was answered "Yes."

Agropec Trading, LLC, doing business as Allivet, has been the subject of regulatory actions concerning its licenses in other states, specifically related to our Miami Lakes, Florida pharmacy.

A detailed summary of the state actions related to this matter is attached for your review.

I affirm that the above information and the attached documentation are true and correct to the best of my knowledge.

John Jairo Navas – Officer

Signature: _____

Date: 11/13/2024

Allivet
Your Ally in Pet Pharmacy Care

14540 NW 60th Ave
Miami Lakes, FL 33014
Phone 877-500-9944
Fax 877-500-9950
www.allivet.com

State Disciplinary Actions

1. **Oregon - 2008-0097 - 12/09/08**

   The case with the state of Oregon was opened on Dec 9th, 2008, and settled with a consent order dated February 18th, 2009. There was a civil fine of $750 due to Allivet shipping to Oregon in early 2008 without an out of state license. This was an unintentional oversight as Allivet was a new pharmacy and was in the process of obtaining all licenses.

2. **Indiana - 2011 IBP 0053 - 09/28/11**

   Allivet began shipping prescription orders into the state of Indiana while the pharmacy application was still in process. Because of that, Indiana sent a stop-ship order dated September 28th, 2011. Allivet received its out of state pharmacy license from the state of Indiana in December 2011 and was able to continue operating without any further issues.

3. **Alabama-16-L-0130 - 02/28/17**

   This action was a ***derivative action*** referencing the following disciplinary actions:

   - Oregon - 2008-0097 - 12/09/08
   - Indiana - 2011 IBP 0053 - 09/28/11

4. **Colorado - CO-2013-534 - 12/19/13**

   Allivet was fined $1,100 by Colorado for dispensing medications without a wholesale license to a veterinarian. At the time of the incident in 2011, Isoxsuprine was on manufacturer backorder, but Allivet had the product in stock. Due to the product's constrains Allivet was contacted by a veterinarian urgently requiring this medicine for his pet owners in Colorado. Allivet provided the medication, unaware of the wholesale licensing requirements. Allivet does not engage in any wholesale pharmacy transactions to ensure full compliance with state regulations.

5. **Alabama-AL-2015-001 - 10/10/15**

   Allivet applied for a Pharmacist-in-Charge (PIC) license with the Alabama Board of Pharmacy on November 10, 2014, to facilitate the renewal of its pharmacy license for 2015. Alabama scheduled a meeting for Allivet's pharmacist in February 2015, beyond the expiration date of the license on December 31, 2014. To address this, Allivet contacted the Board of Alabama to request an earlier meeting and to confirm that its renewal would not be affected by the schedule. During this time, it was assured that Allivet's pharmacy license would remain in good standing until the in-person meeting, and the Board's website indicated the license as active. Operating under this assumption, Allivet continued shipping products. When questioned about early 2015 shipments, Allivet explained that it believed it was permitted to do so based on prior communications. As a result, Allivet was fined $500 for shipping into the state without an Alabama-licensed Pharmacist-in-Charge.

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6. **Arkansas-AR-2015-049 - 10/13/15**

   In 2015, a technical issue in Allivet's system compromised the designated safety measures to prevent shipment of prescription items without active licenses. As a result, orders placed over the phone were processed and shipped into Arkansas without a valid license in 2015.

7. **Alabama-17-L-0050 - 05/18/17**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

8. **Colorado - 2018-6062 - 08/13/18**

   This action was a ***derivative action*** referencing the following disciplinary action:

   - Arkansas-AR-2015-049 - 10/13/15

9. **Michigan-53-17-148216 - 06/25/18**

   Action I:
   In late 2008, Allivet changed locations and failed to report the change of location within 30 days to the Michigan Board of Pharmacy. This was an unintentional oversight as Allivet had just opened its pharmacy in 2007. At the following renewal date, Allivet noted the new address which triggered the action.

   Action II:
   This action was a ***derivative action*** referencing the following disciplinary actions:
   - Oregon - 2008-0097 - 12/09/08
   - Alabama-AL-2015-001 - 10/10/15
   - Arkansas-AR-2015-049 - 10/13/15

10. **Texas-K-17-031 - 07/09/18**

    Action I:
    This action was a ***derivative action*** referencing the following disciplinary actions:

    - Oregon - 2008-0097 - 12/09/08
    - Indiana - 2011 IBP 0053 - 09/28/11
    - Colorado - CO-2013-534 - 12/19/13

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Action II:
On September 1st, 2016, the Texas Board of Pharmacy changed the requirement for non-resident pharmacies to have a licensed Texas Pharmacist in Charge. Allivet immediately began the process to obtain licensure for its pharmacist, but due to the lengthy process, the license was not granted until May 2017. Therefore, due to the Texas regulatory change, Allivet operated without a Texas-licensed Pharmacist-in-Charge from September 1, 2016, to May 21, 2017. Currently, Allivet holds an active license and is in good standing with the state of Texas.

11. Illinois - 021930788 - 11/05/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Oregon - 2008-0097 - 12/09/08
- Indiana - 2011 IBP 0053 - 09/28/11
- Colorado - CO-2013-534 - 12/19/13
- Alabama-AL-2015-001 - 10/10/15
- Arkansas- AR-205-049 - 10/13/15
- Michigan-53-17-1481216 - 06/25/18
- Texas-K-17-031 - 07/09/18

12. Hawaii-RICO Case No. PHA 2019-79-L - 12/26/19

This action was a ***derivative action*** referencing the following disciplinary actions:

- Texas-K-17-031 - 07/09/18
- Michigan-53-17-148216 - 06/25/18

13. Alabama-19-L-0007 - 01/06/20

This action was a ***derivative action*** referencing the following disciplinary actions:

- Florida Case No. 2008-26608[1]
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Michigan-53-17-148216 - 06/25/18
- Alabama-16-L-0130 - 02/28/17
- Alabama-17-L-0050 - 05/18/17

[1] Original case was under a different pharmacy license, which has no impact or connection to Allivet's current license nor disciplinary history.

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14. Hawaii-RICO Case No. PHA 2020-168-L - 01/18/21

This action was a ***derivative action*** referencing the following disciplinary actions:

- Michigan-53-17-148216 - 06/25/18
- Texas-K-17-031 - 07/09/18
- Colorado - 2018-6062 - 08/13/18
- Illinois- 021930788 - 11/05/19

15. Nebraska - Censure Complaint #20190354 - 07/09/20

This censure derived from selling rabies vaccines to consumers in Nebraska, instead of the prescribing veterinarian. Allivet has since taken down the sales of all rabies vaccines across all 50 states to avoid similar circumstances where the Board changes its stance with this product. Dismissal order matter was approved by Hearing Officer on 07/09/2020.

16. Alabama - Consent Letter - 11/10/21

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20

17. Hawaii - RICO Case No. PHA2022-2-L - 05/25/22

This action was a ***derivative action*** referencing the following disciplinary action:

- Nebraska - Censure Complaint #20190354 - 07/09/20
- Alabama - Consent Letter - 11/10/21

Non-Disciplinary Communications

1. Tennessee – Consent Letter – 01/25/2024 Case No. 2023026981

In June 2023, the company changed the Pharmacist in Charge (PIC) at its Miami facility and as required, notified each State Board of Pharmacy. Unfortunately, the notification sent to Tennessee contained an incorrect date, suggesting that there was a brief period when the Miami facility did not have a PIC. This was merely a clerical error. The company has provided all requested records to the Tennessee Board, along with an affidavit from the PIC, demonstrating compliance with PIC regulations at all times. On October 16, 2024, the Tennessee Attorney General for the Board of Pharmacy communicated that the case was closed. No discipline was imposed.

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Fax 877-500-9950
www.allivet.com

2. **Missouri – Letter of Concern – 03/28/2024**

This action was a letter of concern related to the failure to report disciplinary action taken by Hawaii (RICO Case No. PHA2022-2-L; see 17 above). No discipline was imposed.

State of Florida
Department of State

I certify from the records of this office that AGROPEC TRADING, LLC is a limited liability company organized under the laws of the State of Florida, filed on February 22, 2017, effective December 9, 1993.

The document number of this limited liability company is L17000041105.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on January 4, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourth day of January, 2024

Secretary of State

Tracking Number: 6812209961CC

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TRACTOR SUPPLY COMPANY" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

949106 8300

SR# 20244239362

Authentication: 204897649

Date: 11-18-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 15078
Insp # 192463

NAME	PERMIT NUMBER	DATE OF INSPECTION
AGROPEC TRADING, LLC	22570	04/12/2024
DOING BUSINESS AS ALLIVET		
STREET ADDRESS 14540 NW 60th Avenue	**TELEPHONE #** 305-405-8506	**EXT**
CITY MIAMI LAKES	**COUNTY**	**STATE/ZIP** FL/33014

Additional Information

Business Operation Hours

Monday Hours 7:00 am to 5:00 pm	Tuesday Hours 7:00 am to 5:00 pm
Wednesday Hours 7:00 am to 5:00 pm	Thursday Hours 7:00 am to 5:00 pm
Friday Hours 7:00 am to 5:00 pm	M-T-W-TH-F Y
Monday Y	Tuesday Y
Wednesday Y	Thursday Y
Friday Y	Saturday N
Saturday Hours Closed	Sunday N
Sunday Hours Closed	

Registered Pharmacist / Intern / Tech

License # RPT 8773	Licensee Name Yadery Limonte
License Type Pharmacy Tech	
License # RPT54964	Licensee Name Evelyn Castro
License Type Pharmacy Tech	
License # RPT 11149	Licensee Name Juan Lezcano
License Type Pharmacy Tech	
License # PS 33017	Licensee Name Stephanie Tallerie
License Type Registered Pharmacists	
License # PS 48499	Licensee Name Runglak Kitiyasavatdi
License Type Registered Pharmacists	
License # RPT 42393	Licensee Name Yanet Diaz Fernnadez
License Type Pharmacy Tech	
License # PS 37066	Licensee Name Glenroy A Purrier
License Type Registered Pharmacists	
License # RPT 64142	Licensee Name Yoanna Gonzalez Suarez
License Type Pharmacy Tech	
License # RPT 100589	Licensee Name Aylen Leyva Ruiz
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # n/a	

License Relations

RX DPT MGR/COR/POR

KITIYASAVATDI, RUNGLAK	License # 48499

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.]	N/A
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	N/A

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Medicinal Drugs ships thru: USPS, and Fedex. Last CQI meeting conducted on: 02/16/2024. Wholesaler: Zoetis, Merck Animal Health, Elanco Animal Health, Neogen Corp., Vetoquinol USA, American Regent, Kinetic Technologies, McKesson, Animal Health International, MWI Veterinary, Midwest Vet, Vedco, Anda, Blupax Pharma, First Vet, PetIQ, Proficientrx, OK, River City, Second Source RX.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CASTILLO, ELIZABETH

Date:4/12/2024

Representative:

Runglak Kitiyasavatdi PDM

Date:4/12/2024

AC# 11399318

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/04/2023	PH 22570	133923

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy
6:1 Pharmacy Technician Ratio Approved

Expiration Date: **FEBRUARY 28, 2025**
AGROPEC TRADING, LLC
Allivet
14540 NW 60TH AVENUE
MIAMI LAKES, 33014

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

EXPIRATION DATE: **FEBRUARY 28, 2025**

Your license number is PH 22570. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes, request duplicate licenses and much more.

It's simple. Log onto your MQA Online Services account today at http://flhealthsource.gov/. Select the "Account Login" button to access your account. For changes to your name, address or to request duplicate licenses, choose your selection from the dropdown list under "Manage My License". Your profession will open for renewal 90 days prior to your expiration date. When the renewal cycle opens for your profession, the "Renew My License" header will automatically display on your license Dashboard.

IMPORTANT ANNOUNCEMENTS

ARE YOU RENEWAL READY?

The Department of Health will now review your continuing education records at the time of license renewal.

To learn more, please visit
www.FLHealthSource.gov/AYRR

GROUNDS FOR DISCIPLINE

You should be familiar with the Grounds for Discipline found in Section 456.072(1), Florida Statutes, and in the practice act for the profession in which you are licensed. Florida Statutes can be accessed at www.leg.state.fl.us/Statutes

AC# 11399318
STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
DATE 01/04/2023 | LICENSE NO. PH 22570 | CONTROL NO. 133923
THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.
Expiration Date : FEBRUARY 28, 2025
AGROPEC TRADING, LLC
Allivet
QUALIFICATION(S):
Community Pharmacy
6:1 Pharmacy Technician Ratio Approved

October 17, 2024

Luis A Riera
Allivet
14540 Nw 60Th Ave
Miami Lakes, FL 33014

RE: License Certification for Agropec Trading, Llc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH22570
ORIGINAL CERTIFICATION:	02/27/2007
EXPIRATION DATE:	02/28/2025
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

LIST OF OFFICERS

CURRENT OFFICERS

Allivet, Inc.
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

Agropec Trading, LLC
Peter Batushansky-President
Khaled Abdalla-Secretary and Treasurer

POST-CLOSE OFFICERS[1]

Tractor Supply Company[2]
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Seth Estep-Executive Vice President-Chief Merchandising Officer

Allivet, Inc.
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

Agropec Trading, LLC
•Harry A. Lawton, III-President and Chief Executive Officer
•Kurt D. Barton-Executive Vice President-Chief Financial Officer and Treasurer
•Robert D. Mills-Director and Executive Vice President-Chief Technology, Digital Commerce and Strategy Officer
•Noni L. Ellison-Director and Senior Vice President-General Counsel and Corporate Secretary
•Ujjwal S. Dhoot-Officer
•John J. Navas-Officer

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[1] Note that the list of officers for Allivet, Inc. and Agropec Trading, LLC is a comprehensive list. However, the list of officers for Tractor Supply is an abbreviated list.
[2] A comprehensive list of officers of Tractor Supply's can be found on the Investor Relations webpage at: https://ir.tractorsupply.com/investor-relations/governance/executive-management/default.aspx

List of Top four Stockholders and their percentage of Ownership:

Agropec Trading LLC dba Allivet
Allivet, Inc. – 100%

Allivet, Inc.
Tractor Supply Company – 100%

Tractor Supply Company
Vanguard Group - 11.86%
Black Rock, Inc. – 8.93%
Capital international Investors – 6.09%
Capital World Investors – 5.42%

Corporate Structure

Pre-Close

Allivet, LLC
(the "Seller")

Allivet, Inc.
(the "Company")

Agropec Trading, LLC
(the "Operating Subsidiary")

Pharmacy Licenseholder

Post-Close

Tractor Supply Company

Allivet, Inc.
(the "Company")

Agropec Trading, LLC
(the "Operating Subsidiary")

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Agropec Trading, LLC dba Allivet

Pharmacy/Wholesaler License # (if applicable): Nevada Pharmacy License # PH02568

Physical Address: 14540 NW 60th Avenue

City: Miami Lakes State: Florida Zip: 33014

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 877-500-9944 Website: www.allivet.com

Licensing Company Email: compliance@allivet.com

Section 2: Personal Information

First: Runglak Middle: N/A Last: Kitiyasavatdi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Davie State: FL Zip: 33314

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		08/2008 - 08/2010	
Address	**City**	**State**	**Zip**
3300 S. University Dr	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Doctor of Pharmacy (Pharm.D.)			

School Name		From - To (MM/YY – MM/YY)	
Mahidol University		06/2000 - 06/2005	
Address	**City**	**State**	**Zip**
477 Si Ayutthaya Rd	Ratchathewi	Bangkok	10400
Diploma/Degree obtained, if any			
Bachelor Degree of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Triam Udom Suksa Pattanakarn School		06/1998 - 06/2000	
Address	**City**	**State**	**Zip**
499 Phattanakarn 58	Suan Luang	Bangkok	10250
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/24 to Present	[redacted]	Davie	FL	33314
07/19 - 03/24	[redacted]	Davie	FL	33328
07/18 - 06/19	[redacted]	Davie	FL	33328
05/17 - 06/18	[redacted]	Davie	FL	33328
05/14 - 04/17	[redacted]	Sunny Isles Beach	FL	33160
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Agropec Trading, LLC dba Allivet			11/2017 - Present	
Business Address		**City**	**State**	**Zip**
14540 NW 60th Avenue		Miami Lakes	FL	33014
Phone	**Title**		**Number of Employed Hours**	
8775009944	Pharmacist in Charge		14,560 hrs	
Description of Duties				
Reviewing prescriptions and ensuring pharmacy compliance with state regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Rx Pro Pharmacy & Compounding			05/2012 - 11/2017	
Business Address		**City**	**State**	**Zip**
936 W. Hallandale Beach Blvd		Hallandale	FL	33009
Phone	**Title**		**Number of Employed Hours**	
9544550004	Pharmacist in Charge		10,400 hrs	
Description of Duties				
Non sterile compounding, reviewing prescription and ensuring pharmacy compliance with state regulations.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Runglak Kitiyasavatdi **, certify that as the designated representative for**

Agropec Trading, LLC dba Allivet ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RK I am at least 21 years of age;
3. RK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Runglak Kitiyasavatdi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Runglak Kitiyasavatdi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-dade

I, Runglak Kitiyasavatdi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/24

Date

Subscribed and Sworn to before me this 20th day of 2024.

Notary Public Signature

NOTARY PUBLIC STATE OF FLORIDA
Expires 11/29/2025
Anabel Moliner
My Commission HH 203043
(Seal)

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Long-term care	☐ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FA7535923 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☒ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AmeriPharma MedBox

Physical Address: 23041 Avenida De La Carlota, Ste 310

City: Laguna Hills State: CA Zip: 92653

Mailing Address (if different from physical address): Same as physical

City: _____ State: _____ Zip: _____

Telephone: 800-270-7091 Toll Free # (NAC 639.708, NRS 639.23286): 800-270-7091

Fax: 714-464-4410 Contact Email: compliance@medbox.com

Website: www.medbox.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Laemsing Root

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24152

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Laemsing Root	NV Pharmacist Registration #: 24152
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): _____

Corporation/Organization Name: Harper's Pharmacy, Inc.

Mailing Address: 132 South Anita Dr.

City: Orange State: CA Zip: 92868

Telephone: 877-778-3773 Email: compliance@medbox.com

Contact Person Name: Farah Kadduh

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the COO/Owner (title) for AmeriPharma MedBox (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Andrew Harper

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/3/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Andrew Harper hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the COO/Owner (title) for AmeriPharma MedBox (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3rd day of June, 2024

Notary Public

PHILIP ANDREW HORN
COMM. # 2423880
NOTARY PUBLIC - CALIFORNIA
COUNTY OF ORANGE
MY COMM. EXP. NOV. 21, 2026

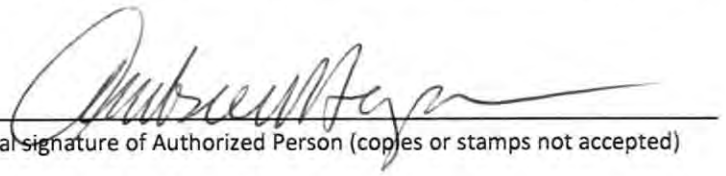
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California, County of Orange
Subscribed and sworn to (or affirmed) before me
on this 3rd day of June, 2024.
by Andrew Harper.
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.
Signature:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Harper

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

6/3/24

Date

Board Use Only	Date Received: 6/10/24	Amount: $500-CC116594

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	HARPER'S PHARMACY, INC.
Entity No.:	3151229
Registration Date:	06/26/2008
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 12, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 228152833

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59230

NAME: AMERIPHARMA MEDBOX

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

23041 AVENIDA DE LA CARLOTA #310
LAGUNA HILLS CA 92653
ORANGE COUNTY

ISSUANCE DATE

DECEMBER 29, 2023

EXPIRATION DATE

DECEMBER 1, 2025

CURRENT DATE / TIME

DECEMBER 4, 2024
10:23:45 AM

LICENSE RELATIONSHIPS

NAME: ROOT, LAEMSING NGUYEN

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 63188 **PRIMARY STATUS:** CLEAR

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy	X	Hospital Pharmacy	Clinic	Exempt Hospital	Wholesaler	Hypodermic

Date: 3/12/2024 • Inspector: Elham Delune

Firm: AMERIPHARMA MEDBOX Phone:

Address: 23041 AVENIDA DE LA CARLOTA #310 City: LAGUNA HILLS Zip: 92653

Ownership: CORPORATION

Permit #: PHY59230 Permit Exp: 5/15/2024 DEA#: FA7535923 DEA Exp: 6/30/2024

Date of Self Assessment Form: 12/3/2024 Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 6AM-5:30PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC LAEMSING N ROOT RPH63188 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
NGOC L HAN	RPH76391	**BRIANNA M ROBERSON**	TCH133570
		JESSICA M ORTIZ	TCH142677
		LISETTE J AGAS	TCH84017
		TAMI S DORSETT	TCH2300

Inspector Remarks:

This is a retail pharmacy located inside medical building.
Typically Staffed: 1 RPH, 5 Clerks.(currently no inventory of Drug, once business grows 2 RPH, 2 TCHs).
WLS: ABC
R/D: RX Revers
Delivery via pharmacy driver (70 miles distance) or FedEx and Out-of-State (USPS, UPS, FedEx)
No compounding
No vaccines
No inventory of drugs. In the process of getting contacts.
Trying to get licensed in 44 states.

Items Reviewed:

This location currently is supporting the AmeriPharma (PHY53838, located in Orange) until they receive insurance contacts. Currently the clerks are processing prescriptions for the Orange location and RPH is verifying prescriptions for the Orange location.

-Self-assessment, permit, email registered with the board, policy and procedures (in place),security, name tags, RPH and TCH ratio.

Discussions

• **Consultation. Delivery** requested to add hours.(CCR 1707.2 (b)(1) .

• California Code of Regulations, section 1717.5 , regarding Automatic Refill Programs. The new regulation is **effective July 1, 2022**.

Topics to Educate

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical

INSPECTION REPORT

guidelines published by FDA in providing these patient care services.

- A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
- Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
- Retain records for 3 years.

2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.
3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.*, any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.*, before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.
5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.
Please provide the following to

Please provide the following documents to inspector Delune at elham.delune@dca.ca.gov within 7-14 days:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- The following Policy and Procedures: Quality Assurance (4125/1711),Tech Job Description (1793.2),Impaired employee/Theft+diver/14day- (4104 c),Temp absence of RPh (1714.1(f) (e).
- Sample Consultation. Delivery (CCR 1707.2 (b)(1) .

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Ngoc

Pharmacist (print) Ngoc Han

Inspector (sign) _____

Inspector (print) E. Dalina

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

List of Officers

AmeriPharma MedBox
23041 Avenida de la Carlota
Ste 310
Laguna Hills, CA 92653

Executive Officers:

Andrew Harper, Pharm. D.
License# RPH 56860
COO/Owner (51%)
[redacted], Azusa, CA 91702

Gor Mnatsakanyan, Esq.
Secretary/Owner (49%)
[redacted], Irvine, CA 92612

Hayk Mnatsakanyan
CEO
[redacted], Irvine, CA 92612

David Dreyer
CFO
[redacted], San Juan Capo, CA 92675

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AmeriPharma MedBox

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 23041 Avenida De La Carolota, Suite 310

City Laguna Hills State CA Zip 92653

Mailing Address (if different from physical address) 23041 Avenida De La Carolota, Suite 310

City Laguna Hills State _____ Zip _____

Telephone 800-270-7091 Website https://medbox.com/

Licensing Company Email support@medbox.com

Section 2: Personal Information

First Laemsing Middle Nguyen Last Root

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]

City Santa Ana State CA Zip 92705

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Touro University College of Pharmacy		9/1/05-6/9/2009	
Address	**City**	**State**	**Zip**
310 Club Dr.	Vallejo	CA	94592
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of California, Los Angeles		9/1/97-6/8/2001	
Address	**City**	**State**	**Zip**
405 Hilgard Ave	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
Bachelor of Arts, English Literature			

School Name		From - To (MM/YY – MM/YY)	
Bolsa Grande High School		9/1/93-6/30/97	
Address	**City**	**State**	**Zip**
9401 Westminster Blvd.	Garden Grove	CA	9284
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2019-current	[redacted]	Santa Ana,	CA	92705
01/1/2014-10/30/20	[redacted]	Union City,	CA	94587

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
AmeriPharma MedBox			4/1/24-current	
Business Address		**City**	**State**	**Zip**
23041 Avenida De La Carlota, Ste 310		Laguna Hills	CA	92653
Phone	**Title**		**Number of Employed Hours**	
800-270-7091	Pharmacist-in-charge		1557 hours	
Description of Duties				
Pharmacist in Charge				

Business Name			From - To (MM/YY – MM/YY)	
AmeriPharma			2/9/2023- 4/1/24	
Business Address		**City**	**State**	**Zip**
132 S. Anita Dr. Ste 210		Orange	CA	92868
Phone	**Title**		**Number of Employed Hours**	
800-270-7091	Pharmacist		2253 hours	
Description of Duties				
Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
NowRx			11/1/2019-12/31/2022	
Business Address		**City**	**State**	**Zip**
1641 Kaiser Ave.		Irvine	CA	92614
Phone	**Title**		**Number of Employed Hours**	
949-619-6000	Regional Pharmacy Manager		4506 hours	
Description of Duties				
Regional Pharmacy Manager				

Business Name			From - To (MM/YY – MM/YY)	
NowRx			4/1/2019-10/31/2019	
Business Address		**City**	**State**	**Zip**
1310 Tully Rd.		San Jose	CA	95122
Phone	**Title**		**Number of Employed Hours**	
949-619-6000	Pharmacy Manager		1211 hours	
Description of Duties				
Pharmacy Manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Laemsing Root, **certify that as the designated representative for**

AmeriPharma MedBox,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LR I am at least 21 years of age;
3. LR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Laemsing Root

Print Name (First, Last)

Laemsing Root

Original Signature (electronic, copies or stamps not accepted)

10-10-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Laemsing Root

Print Name (First, Last)

Laemsing Root — 10-10-24

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Laemsing Root, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Laemsing Root — 10-10-24

Original Signature — **Date**

Subscribed and Sworn to before me this 10th day of October 2024

Notary Public Signature

SEE CALIFORNIA JURAT ATTACHED DATE 10/10/2024 INITL

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 10 day of October, 2024, by Laemsing Root,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TERESA D. LEWIS
COMM. # 2415404
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. OCT. 3, 2026

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AmeriPharma MedBox

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 23041 Avenida De La Carlota, Suite 310

City Laguna Hills State CA Zip 92653

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-270-7091 Website https://medbox.com/

Licensing Company Email support@medbox.com

Section 2: Personal Information

First Gor Middle _____ Last Mnatsakanyan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Irvine State CA Zip 92612-5661

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: South Western Law School			From - To (MM/YY – MM/YY): 09/2008 - 05/2011
Address: 3050 Wilshire Blvd,	City: Los Angeles	State: CA	Zip: 90010
Diploma/Degree obtained, if any: Juris Doctor			
School Name: University of California - Los Angeles			From - To (MM/YY – MM/YY): 2005-2007
Address: 405 Hilgard Ave,	City: Los Angeles	State: CA	Zip: 90095
Diploma/Degree obtained, if any: PA Philosophy			
School Name: Los Angeles Valley College			From - To (MM/YY – MM/YY): 2002-2004
Address: 5800 Fulton Ave,	City: Valley Glen	State: CA	Zip: 91401
Diploma/Degree obtained, if any: Transfer Program/ Philosophy			
School Name: Grand highschool			From - To (MM/YY – MM/YY): 2000-2002
Address: 13000 Oxnard St,	City: Van Nuys	State: CA	Zip: 91401
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 - Present	[redacted]	Irvine	CA	92612-5661
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Harper's Pharmacy, Inc			2011 - Present	
Business Address		**City**	**State**	**Zip**
132 S.Anita Dr.,		Orange	CA	92868
Phone	**Title**			
877-778-3773	Secretary			
Description of Duties				
Owner, Officer, Legal Secretary				

Business Name			From - To (MM/YY – MM/YY)	
Gor & Associates PC			2012 - Present	
Business Address		**City**	**State**	**Zip**
3435 Wilshire Blvd, #1710		Los Angeles	CA	90010
Phone	**Title**			
310-601-3131	Managing Attorney			
Description of Duties				
Owner, Managing Attorney				

Business Name			From - To (MM/YY – MM/YY)	
Center for Truth & Justice				
Business Address		**City**	**State**	**Zip**
2100 Montrose Ave #715		Montrose	CA	91020
Phone	**Title**			
310-601-3131	President of Board of Directors			
Description of Duties				
President				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gor Mnatsakanyan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Gor Mnatsakanyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/5/24

Date

Subscribed and Sworn to before me this 5 day of September.

Notary Public Signature

SEE CALIFORNIA JURAT ATTACHED
DATE 09/05/2024 INITL

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 5th day of September, 2024, by Gor Mnatsakanyan,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TERESA D. LEWIS
COMM. # 2415404
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. OCT. 3, 2026

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AmeriPharma MedBox

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 23041 Avenida De La Carlota, Suite 310

City Laguna Hills State CA Zip 92653

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-270-7091 Website https://medbox.com/

Licensing Company Email support@medbox.com

Section 2: Personal Information

First Andrew Middle Allen Last Harper

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Azusa State CA Zip 91702

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Albany College of Pharmacy & Health Services, Albany NY		2001 - 2004	
Address	**City**	**State**	**Zip**
106 New Scotland Ave.,	Albany	NY	12208
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
State University at New York, Oswego, NY		1997-2001	
Address	**City**	**State**	**Zip**
7060 NY 104,	Oswego	NY	13126
Diploma/Degree obtained, if any			
Bachelor of Arts in Biology			

School Name		From - To (MM/YY – MM/YY)	
Ogdensburg Free Academy		Until 1997	
Address	**City**	**State**	**Zip**
1100 State St,	Ogdensburg	NY	13669
Diploma/Degree obtained, if any			
High School Degree			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2009 - Present	[redacted]	Azusa	CA	91702-6265
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Harper's Pharmacy, Inc.			August 2023 - Present
Business Address	**City**	**State**	**Zip**
132 S.Anita Dr.,	Orange	CA	92868
Phone	**Title**		
877-778-3773	COO		
Description of Duties			
Owner/ Officer/ Management of Operations			

Business Name			From - To (MM/YY – MM/YY)
Harper's Pharmacy, Inc.			2008 - August 2023
Business Address	**City**	**State**	**Zip**
132 S.Anita Dr.,	Orange	CA	92868
Phone	**Title**		
877-778-3773	CEO		
Description of Duties			
Owner/ Officer/ Management of Operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Harper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange.

I, Andrew A. Harper, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/5/24

Date

Subscribed and Sworn to before me this 5th day of September 2024.

Notary Public Signature

SEE CALIFORNIA JURAT ATTACHED
DATE 09/05/2024 INITL

(Seal)

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State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 5th day of September, 2024, by Andrew Allen Harper,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TERESA D. LEWIS
COMM. # 2415404
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. OCT. 3, 2026

(Seal)

Signature

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty Pharmacy	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Specialty Pharmacy

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BioPlus Specialty Pharmacy Services, LLC

Physical Address: 4900 Prospectus Dr. Suite 300

City: Durham State: NC Zip: 27713

Mailing Address (if different from physical address): P O Box 162088

City: Altamonte Springs State: FI Zip: 32716-2088

Telephone: 866-514-8082 Toll Free # (NAC 639.708, NRS 639.23286): 866-514-8082

Fax: 833-664-4926 Contact Email: license@bioplusrx.com

Website: www.bioplusrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Bryan Monroe

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24393

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Bryan Monroe	NV Pharmacist Registration #: 24393
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): BioPlus Parent, LLC

Corporation/Organization Name: BioPlus Specialty Pharmacy Services, LLC

Mailing Address: 220 Virginia Ave

City: Indianapolis State: Indiana Zip: 46204

Telephone: 317-488-6000 Email: license@bioplusrx.com

Contact Person Name: Kimberly Bourcier

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Amy Mulderry

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/2/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Bryan Monroe hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25th day of November, 20 24

Notary Public

NORIS MARIA PEREZ DE TINOCO
NOTARY PUBLIC
ALAMANCE COUNTY, NC

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Mulderry - Manager

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/2/2024

Date

Board Use Only	Date Received: 12/5/24	Amount: $500 ck 63186441

State of Florida
Department of State

I certify from the records of this office that BIOPLUS SPECIALTY PHARMACY SERVICES, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 6, 2020, effective December 28, 1988.

The document number of this limited liability company is L20000120596.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on March 19, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eleventh day of June, 2024

Secretary of State

Tracking Number: 2601402531CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Inspection Details

Name	BioPlus Specialty Pharmacy Services, LLC	**Case #**		**Permit**	15118
		Person Providing Info	Bryan Douglas Monroe	**Inspection Date**	08/22/2024
Address	4900 Prospectus Dr Durham, NC 27713	**Person In Charge**	Bryan Douglas Monroe	**Inspection User**	Junez, Ruben
		Rx Volume/Date	Roughly 40 to 50 prescriptions a day.	**Inspection District**	DISTRICT3
# RPhs	2 pharmacists				
# Techs	2 technicians	**Hours**	M-F 8 AM to 5 PM		
Follow-Up CAP	No	**Office**	No		
CAP Requested	No	**Commercial Use**	No		
CAP Documentation Received	No	**Ship to Other States**	Yes		
Additional Documents	Yes	**States Shipped To**	Arizona, Ohio, Indiana, Virgin Islands, Maine, Wisconsin, Rhode Island, New Jersey, Delaware, New Hampshire, Florida, DC, North Carolina, Massachusetts.		
Office Use	No				
Office Use Comments					
		Commercial Use Documented Clinical Indication	No		

Non-Sterile Compounding

Non-Sterile No

Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?

Does facility engage in moderate or complex sterile compounding?

Does facility engage in Hazardous Drug Compounding?

Is there documented clinical indication for the approved medication?

Sterile Compounding

Sterile Compounding No

Does facility compound Immediate Use CSP?

Does facility compound Category 1 Sterile Compounding?

Does facility compound Category 2 Sterile Compounding?

Does facility compound Category 3 Sterile Compounding?

Does facility compound hazardous medications?

Does facility compound Allergenic Extracts?

Pharmacy Staffing

How many pharmacists are employed at the pharmacy: 2 pharmacists

How many technicians are employed at the pharmacy: 2 technicians

What is the P:T ratio at the time of inspection: 1:1

How often is there only one pharmacist on duty:

If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift: Not above

How many technicians are usually on shift at a time: Usually 2 technicians per shift.

What is the approved Pharmacist: Technician ratio? N/A

Are pharmacists asked to do any duties outside of the pharmacy :

Pharmacy Volume

What is the average daily prescription volume of the pharmacy: Roughly 40 to 50 prescriptions a day.

Does pharmacy conduct any point of care testing such as COVID: No

Does pharmacy administer vaccines: No

What is the daily average of testing:

What is the daily average of vaccines:

What staff is responsible for administering test and what is testing procedure:

What staff members are administering vaccines and what

type of vaccines:

Are administered vaccines reported to the appropriate vaccine registry:

How far behind is the pharmacy on filling and verifying prescriptions:

N

Please explain:

How long has this backlog persisted:

Comments

EnterpriseRx through McKesson is the dispensing software used.
UPS is the primary courier and FedEx is used for some prescriptions. The facility does have a medical courier that they use on emergency cases.
Pharmalink is the reverse distributor.

General Pharmacy Regulations

	Answer	Question
1)	Satisfactory	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2)	Satisfactory	NCGS 90-85.15A (b) – Current registration of a pharmacy tech shall be readily available for inspection
3)	Satisfactory	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
4)	Satisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
5)	Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
6)	Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
7)	Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
8)	Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
9)	Satisfactory	NCGS 90-85.47 - Quality Assurance Program
		Comments: Program Qualitize used for Quality Assurance.
10)	Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
		Comments: Closed door specialty pharmacy facility.
11)	Satisfactory	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
12)	Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
		Comments: Closed door specialty pharmacy facility.
13)	Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
		Comments: Closed door specialty pharmacy facility.
14)	Satisfactory	NCGS 90-640 (b) - ID badge
15)	Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
16)	Satisfactory	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
17)	Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
18)	Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
19)	Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.

General Pharmacy Regulations

	Answer	Question
20)	Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
21)	Satisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
22)	Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
23)	Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
24)	Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
25)	Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
26)	Satisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
27)	Satisfactory	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
28)	Satisfactory	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
29)	Satisfactory	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
30)	Not Applicable	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
		Comments: Facility does not dispense controls.
31)	Not Applicable	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
		Comments: Facility does not dispense controls.
32)	Not Applicable	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
		Comments: Facility does not dispense controls.
33)	Not Applicable	21CFR 1305.05 (a) - power of attorney on file at registered location.
		Comments: Facility does not dispense controls.
34)	Not Applicable	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
		Comments: Facility does not dispense controls.
35)	Satisfactory	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
36)	Satisfactory	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
37)	Satisfactory	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
38)	Not Applicable	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed

General Pharmacy Regulations

	Answer	Question
39)	Not Applicable	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner.
40)	Not Applicable	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
41)	Not Applicable	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
42)	Not Applicable	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
43)	Not Applicable	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
44)	Not Applicable	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
45)	Not Applicable	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
46)	Not Applicable	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
47)	Not Applicable	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
48)	Not Applicable	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

NORTH CAROLINA BOARD OF PHARMACY

Facility: BioPlus Specialty Pharmacy Services, LLC
Address: 4900 Prospectus Dr Suite 300 Durham, NC 27713
Permit Type: Pharmacy
Permit #: 15118
Re-Issue Date: 05/13/2024
Expiration Date: 12/31/2024
Pharmacy Manager: Bryan Douglas Monroe (#13972)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 15118

NORTH CAROLINA BOARD OF PHARMACY

2024 Pharmacy

This is to certify that

BioPlus Specialty Pharmacy Services, LLC

doing business as

BioPlus Specialty Pharmacy Services, LLC

4900 Prospectus Dr Suite 300 Durham, NC 27713 Durham

Has been renewed for the year ending December 31st 2024, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Bryan Douglas Monroe (#13972)

05/13/2024
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

North Carolina Board of Pharmacy

Only the top 250 records are shown

This serves as Primary Source Verification of the credential issued by the North Carolina Board of Pharmacy

Name:	BioPlus Specialty Pharmacy Services, LLC	**Permit #:**	15118
Address:	4900 Prospectus Dr Suite 300	**Permit Status:**	Active
City:	Durham	**Issue Date:**	02/15/2023
State/Zip:	NC 27713	**Expire Date:**	12/31/2024
Manager:	Bryan Douglas Monroe	**Discipline:**	No

Information loaded from this database is current as of 12/4/2024 12:50:45 PM

BioPlus
Specialty Pharmacy

Ownership

BioPlus Parent, LLC – 100% Direct Owner

220 Virginia Avenue
Indianapolis, IN 46204
Tax ID: 85-0609453

BioPlus Parent, LLC – Director/Manager List

Amy Mulderry
[redacted]
New York, NY 10128
0% ownership interest

Danielle Anne Swenson
[redacted]
Ship Bottom, NJ 08008
0% ownership interest

Vincent Edward Scher
[redacted]
Indianapolis, IN 46280
0% ownership interest

BioPlus Parent, LLC – Officer List

Amy Mulderry – President
[redacted]
New York, NY 10128
0% ownership interest

Kathleen Susan Kiefer – Secretary
[redacted]
Indianapolis, IN 46240
0% ownership interest

Vincent Edward Scher - Treasurer
[redacted]
Indianapolis, IN 46280
0% ownership interest

Eric Kenneth Noble – Assistant Treasurer
[redacted]
Indianapolis, IN 46260
0% ownership interest

BioPlus Specialty Pharmacy Services, LLC
Tax ID#59-2920860

Directors/Manager

Amy Mulderry
[redacted]
New York, NY 10128
0% ownership interest

Danielle Anne Swenson
[redacted]
Ship Bottom, NJ 08008
0% ownership interest

Vincent Edward Scher
[redacted]
Indianapolis, IN 46280
0% ownership interest

Officers

Amy Mulderry (President)
[redacted]
New York, NY 10128
0% ownership interest

Vincent Edward Scher (Treasurer)
[redacted]
Indianapolis, IN 46280
0% ownership interest

Kathleen Susan Kiefer (Secretary)
[redacted]
Indianapolis, IN 46240
0% ownership interest

Eric Kenneth Noble (Assistant Treasurer)
[redacted]
Indianapolis, IN 46260
0% ownership interest

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: BioPlus Specialty Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 4900 Prospectus Dr. Suite 300

City: Durham State: NC Zip: 27713

Mailing Address (if different from physical address): PO Box 162088

City: Altamonte Springs State: FL Zip: 32716-2088

Telephone: 866-514-8082 Website: www.bioplusrx.com

Licensing Company Email: license@bioplusrx.com

Section 2: Personal Information

First: Bryan Middle: Douglas Last: Monroe

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Raleigh State: NC Zip: 27614

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina - Chapel Hill		08/94-05/97	
Address	City	State	Zip
301 Pharmacy Ln	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Appalachian State University		08/92-05/94	
Address	City	State	Zip
287 Rivers St	Boone	NC	28608
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Hoke County High School		09/88-05/92	
Address	City	State	Zip
505 S. Bethel Rd.	Raeford	NC	28376
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/03-11/24	[redacted]	Raleigh	NC	27614
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioPlus Specialty Pharmacy			11/18-11/24	
Business Address		**City**	**State**	**Zip**
4900 Prospectus Dr. Ste. 300		Durham	NC	27713
Phone	**Title**		**Number of Employed Hours**	
919-268-1476	Manager Pharmacist in Charge		12,480	
Description of Duties				
Pharmacist-Manager managing all aspects of pharmacy, including dispensing, distribution, regulatory compliance, and managing pharmacists and ancillary staff.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/30/1998	03/08/1999	NC	Carrboro	Orange
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		North Carolina Board of Pharmacy		
Reason/Charge				
violation of 21 NCAC 46.2504 (patient counseling rule)				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

In March 1999, I was disciplined by the North Carolina Board of Pharmacy for a violation of 21 NCAC 46.2504 in November 1998. An undercover investigator with the Board presented a prescription and was not offered counseling on that prescription. The pharmacy's procedure at the time of dispensing was that the pharmacy technician would make the offer to counsel on behalf of the pharmacist, but inadequate training on how to make a positive offer to counsel to encourage acceptance resulted in this violation. At a prehearing conference that I attended along with my Pharmacist-Manager and another pharmacist, who were also found in violation, I accepted the Board's disciplinary action as reflected in the attached document. I was involved in restructuring the policy and training provided by the pharmacy and no further violations have occurred. As a result of this incident, I have ensured throughout my career that my patients are appropriately counseled and that policies are in place to ensure a high level of pharmaceutical care. I have not had any other disciplinary actions of any kind since this occurrence.

Original Signature (electronic, copies or stamps not accepted)

11/25/2024
Date

I, Bryan Douglas Monroe, **certify that as the designated representative for**

BioPlus Specialty Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bryan Monroe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/25/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bryan Monroe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Durham

I, Bryan Monroe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/25/2024

Date

Subscribed and Sworn to before me this 25th day of November, 2024

Notary Public Signature

NORIS MARIA PEREZ DE TINOCO
NOTARY PUBLIC
ALAMANCE COUNTY, NC
(Seal)

NORTH CAROLINA BOARD OF PHARMACY

Licensee: Bryan Douglas Monroe
License Type: Pharmacist
License #: 13972
Re-Issue Date: 12/29/2023
Expiration Date: 12/31/2024

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

License #: 13972

NORTH CAROLINA BOARD OF PHARMACY

2024

Pharmacist

This is to certify that

Bryan Douglas Monroe

Is registered and entitled to practice as a Pharmacist as authorized under the North Carolina Pharmacy Practice Act for the year ending December 31st, 2024. This certificate is revocable for the causes specified in the law and must be conspicuously displayed in the pharmacy where holder practices.

IN WITNESS WHEREOF, The President and Executive Director Hereunto Affix Their Signatures

PRESIDENT

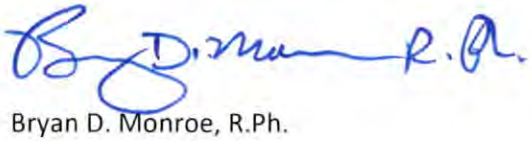
12/29/2023
Re-Issued

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

Personal Statement regarding discipline from NC Board of Pharmacy in March 1999

In March 1999, I was disciplined by the North Carolina Board of Pharmacy for a violation of 21 NCAC 46.2504 in November 1998. An undercover investigator with the Board presented a prescription and was not offered counseling on that prescription. The pharmacy's procedure at the time of dispensing was that the pharmacy technician would make the offer to counsel on behalf of the pharmacist, but inadequate training on how to make a positive offer to counsel to encourage acceptance resulted in this violation. At a prehearing conference that I attended along with my Pharmacist-Manager and another pharmacist, who were also found in violation, I accepted the Board's disciplinary action as reflected in the attached document. I was involved in restructuring the policy and training provided by the pharmacy and no further violations have occurred. As a result of this incident, I have ensured throughout my career that my patients are appropriately counseled and that policies are in place to ensure a high level of pharmaceutical care. I have not had any other disciplinary actions of any kind since this occurrence.



Bryan D. Monroe, R.Ph.

NC Pharmacist License 13972

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter Of:

DRUGS AMERICA	)	
(Permit No. 4945)	)	
	)	
JULIE DELLA- MEA	)	
(Licence No. 11332)	)	
	)	CONSENT ORDER
JASON MICHAEL FOIL	)	
(License No. 14357)	)	
	)	
BRIAN DOUGLAS MONROE	)	
(License No. 13972)	)	

On March 8, 1999, the North Carolina Board of Pharmacy issued notice to Drugs America, Julie Della-Mea, Jason Foil and Brian Monroe, pursuant to 21 North Carolina Administrative Code 46.2008, which scheduled a pre-hearing conference for March 25, 1999, at the Board office, 104-C Carrboro Plaza, Hwy. 54 Bypass, Carrboro, NC. The pre-hearing conference was scheduled in response to investigative findings suggesting that pharmacists at Drugs America had committed acts in violation of 21 NCAC 46.2504.

On March 25, 1999, the pre-hearing conference was conducted as scheduled. RPh. Della-Mea, Foil and Monroe were present without counsel. RPh. Dwight Ayscue was present for the permit. Present for the Board were Board member Robert Crocker, Director of Investigations Steve Hudson, and Board Investigators Josh Kohler and Lisa Dumire. Investigators Kohler and Dumire presented the investigative findings in this matter. After consideration of those findings and the pharmacist's response, Mr. Crocker proposed the following Finding of Fact, Conclusion of Law, and Disciplinary Action.

FINDING OF FACT

1. Jason Michael Foil (Respondent Foil) was issued license number 14357 by the Board on June 26, 1998. RPh. Brian Douglas Monroe (Respondent Monroe) was issued license number 13972 by the Board on July 1, 1997. Drugs America (Respondent permit) was issued permit number 4945 by the Board on April 5, 1988 and last renewed on December 11, 1998 with RPh. Julie Della-Mea as the RPh. Manager.

2. On November 12, 1998, Respondent Foil dispensed Erythromycin to Investigator Dumire, who was working in an undercover capacity, without making an offer to counsel her about the product.

3. On November 30, 1998, Respondent Foil dispensed Erythromycin to Investigator Kohler, who was working in an undercover capacity, without making an offer to counsel him about the product.

4. On November 30, 1998, Respondent Monroe dispensed Doxycycline to Investigator Dumire, who was working in an undercover capacity, without making an offer to counsel her about the product.

5. Respondent permit and Respondents Foil and Monroe hereby waive any further Finding of Fact in this matter.

CONCLUSION OF LAW

Respondent permit and Respondents Foil and Monroe admit that they have violated 21 NCAC 46.2504 and that this conduct constitutes sufficient grounds for disciplinary action by the Board under GS 90-85.38 (a), (6), and (7).

Based on the foregoing, and with the consent of Respondents, IT IS THEREFORE THE

ORDER OF THE BOARD

1. That the permit issued to RPh. Julie Della-Mea and Mast Drug Company is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

    I. The permit be actively suspended for a period of one (1) business day beginning no later than 90 days after the Board's acceptance of this Order.

II. That no laws governing the practice of pharmacy shall be violated at this location during the stay period.

III. That no violation of Board rules shall be violated at this location during the stayed period.

IV. That a sign be conspicuously displayed on the entrance to the pharmacy stating "This Pharmacy Closed By Order of the North Carolina Board of Pharmacy For One Day". Such sign will be furnished by the Board.

V. That Respondent permit shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of the permit.

VI. That each technician employed at the pharmacy be trained in how to comply with 21 NCAC 46.2504.

VII. That a Policy & Procedures manual be constructed which effectively addresses the technician's role in complying with 21 NCAC 46.2504.

VIII. That each technician must indicate successful completion of the training in these Policies & Procedures by his/her signature in the manual.

2. That the license issued to Respondent Foil is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

I. That the license be actively suspended for a period of three (3) business days beginning no later than 90 days of the Board's acceptance of this Order.

II. That during the stay period Respondent Foil shall violate no laws governing the practice of pharmacy.

III. That during the stay period Respondent Foil violate no rules of the Board of Pharmacy.

IV. That Respondent Foil shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of his license. Such notification shall be in writing and directed to the North Carolina Board of Pharmacy, PO Box 459, Carrboro, NC 27510 or faxed to (919)967-5757. He shall surrender his license, the renewal certificate thereof, and his wallet card to the Board during the active suspension period.

3. That the license issued to Respondent RPh. Monroe is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

I. That the license be actively suspended for a period of three (3) business days beginning no later than 90 days of the Board's acceptance of this Order.

II. That during the stay period Respondent Monroe shall violate no laws governing the practice of pharmacy during this stayed period.

III. That during the stay period Respondent Monroe violate no rules of the Board of Pharmacy during the stayed period.

IV. Respondent Monroe shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of his license. Such notification shall be in writing and directed to the North Carolina Board of Pharmacy, PO Box 459, Carrboro, NC, 27510 or faxed to (919)967-5757. He shall surrender his license, the renewal certificate thereof, and his wallet card to the Board during the active suspension period.

By order of the North Carolina Board of Pharmacy this the 21st day of April, 1999.

By: Albert F. Lockamy, Jr.
Albert F. Lockamy, Jr.
President

ATTEST:

David R. Work
Executive Director

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB8225763	07-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-08-2024

BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
4900 PROSPECTUS DR STE 300
DURHAM, NC 277134407

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB8225763	07-31-2027	$888

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4900 PROSPECTUS DR STE 300
DURHAM, NC 277134407

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Form DEA-223 (9/2016)

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-State	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Mail Order	☐ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: CarelonRx Pharmacy, Inc.

Physical Address: 4241 Irwin Simpson Rd Ste 500

City: Mason State: Ohio Zip: 45040

Mailing Address (if different from physical address): P.O. Box 162088

City: Altamonte Springs State: Florida Zip: 32716

Telephone: 833-396-0309 Toll Free # (NAC 639.708, NRS 639.23286): 833-396-0309

Fax: 833-310-3762 Contact Email: CarelonRxPharmacyLicensing@carelon.com

Website: https://www.carelonrx.com/

Nevada Business License # (if applicable) NV20212034904

Supervising/Managing Pharmacist Name (NRS 639.220): Stephanie Z. Eckert

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24239

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Stephanie Z. Eckert	NV Pharmacist Registration #: 24239
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): CarelonRx Pharmacy, Inc.

Corporation Name: Elevance Health, Inc. (Ultimate Parent Company, incorporated in Indiana)

Mailing Address: P.O. Box 162088

City: Altamonte Springs State: Florida Zip: 32716

Telephone: 833-396-0309 Email: CarelonRxPharmacyLicensing@carelon.com

Contact Person Name: Kimberly Bourcier

Date of SEC Registration: | SEC Registration Number: 001-16751 | Stock Exchange Symbol: ELV

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Clayton D. Edwards

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Clayton D. Edwards hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Clayton D Edwards
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 16th day of September, 2024

Marsha Sue Brown
Notary Public

MARSHA SUE BROWN
Notary Public - State of Florida
Commission # HH 304419
My Comm. Expires Dec 18, 2026
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Clayton D. Edwards

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted) Date

Board Use Only	Date Received: 12/5/24	Amount: $500-ck 63189022

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CARELONRX PHARMACY, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5688829 8300

SR# 20244177256

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204842612

Date: 11-11-24

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0234000029

Carelonrx Pharmacy, Inc.

4241 Irwin Simpson Rd Ste 500
Mason, OH 45040-9011
Warren County

Terminal - Pharmacy - LIMITED Category 2

Outpatient Pharmacy Inspection

January 19, 2024

License 0234000029 - Carelonrx Pharmacy, Inc.

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Elizabeth Bond
Start 1/19/2024 11:33 AM
End 1/19/2024 2:10 PM

Organization

Name
Carelonrx Pharmacy, Inc.

License Type
Terminal - Pharmacy - LIMITED Category 2

Category

License Number
0234000029

Business Type
CRP - Contract Remote Order Entry

DEA Number

Responsible Person
Tyler Ingle, RPH

Hours of Operation
M-F: 9AM-5PM; Closed Sat & Sun; 24/7 on call

Contact

Address
4241 Irwin Simpson Rd Ste 500
Mason, OH 45040-9011
Warren County

Primary Number
(757) 297-3835

Fax Number

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Tyler Ingle, RPH		Responsible Person	[redacted]		tyler.ingle@carelon.com

1) Initial Inspection Information

1) Document personnel conducting inspection

Observation
Compliance Specialist Elizabeth Bond, RPh

2) Were multiple inspection guides used during this inspection?

No

3) What is the name and current version of the dispensing software being used by the pharmacy?

Observation
EnterpriseRX, version 13.3.0.0

4) Is the dispensing software pharmacy owned, or provided by a third-party vendor?

Third-Party Vendor

5) Facility description

Observation
The licensee is an outpatient only remote order entry pharmacy. The employed pharmacists perform remote order entry verification and call center services for mail order pharmacies. The patient population includes all patients receiving treatment in a ambulatory, outpatient setting. No dangerous drugs, controlled or non-controlled, are purchased, stored, or dispensed by the licensee. The licensee employs 21 pharmacists and 129 pharmacy technicians. The average monthly order volume is approximately 240,000 prescriptions. This is a routine inspection, conducted at the request of the licensee, for the purpose of obtaining licensure in other states. The inspection focused on remote order verification policies and procedures, record keeping, and quality assurance. No issues noted.

2) * Licensing, Responsible Person and DEA Registration

1) Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

2) Is the Responsible Person present during the inspection?

Yes

3) *Does the responsible person match what is indicated in eLicense?

Yes

Observation
RP: Tyler Ingle, RPh

4) *Does the pharmacy have a valid registration issued by the Drug Enforcement Administration?

Not Applicable - Category II license

3) * Minimum Standards

1) Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?

Yes

3) *Are the pharmacy's hours publicly posted?

Yes

4) *Are all pharmacy staff wearing name tags/badges that include the employee's job title?

Yes

5) Does the pharmacy have prescription containers that comply with the Poison Prevention Packaging Act of 1970?

No

7) Are the library and equipment housed in a suitable, well-lit and well-ventilated room or department and maintained in a clean, sanitary and orderly condition?

Yes

8) *Are areas where drugs and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition?

Yes

Observation
The pharmacy does not store dangerous drugs or devices. The space designated as pharmacy space and within the pharmacy barricade meets the above standards.

9) Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?

No

Observation
No drug stock is housed on-site. Current room temperature is 70 degrees F.

10) Are hypodermics stored in the pharmacy kept out of public view?

Not Applicable - hypodermics are not stored in pharmacy

11) Additional Observations/Violations

Observation
Observed Policy and Procedure Manual. The policies are reviewed at least annually. Reviewed Billing- Submission of Federal Health Care Claims policy (CRX-B-502) updated/reviewed on 1/12/2024.
Reviewed Order Processing- Drug Utilization Review (Pharmacist Verification) policy CRX-PO-112 with no issues noted; updated 9-1-2023
Reviewed Professional Practices: Remote Order Processing and Supervision policy CRX-PP-436 with no issues noted, updated 9-1-2023
Reviewed Adoption of Information Security Policies (CRX-RC-306)- 8-25-2023 and Guidelines for Home and Remote Workers (IS-GDL-002)- 3-23-2023 with no issues noted

4) * Personnel

1) *Are staff working at the pharmacy properly licensed/registered with the Board?

Yes

2) Are technician trainees working within their applicable scope of practice?

Not Applicable - no technician trainee working or employed during inspection.

3) Are there enough pharmacists supervising technician trainees?

Not Applicable - No trainees working or employed during inspection.

4) Are registered pharmacy technicians working within their applicable scope of practice?

Yes

5) Are certified pharmacy technicians working within their applicable scope of practice?

Yes

6) Are pharmacy interns working within their applicable scope of practice?

Not Applicable - No pharmacy interns working or employed during inspection.

7) Are there enough pharmacists supervising pharmacy interns?

Not Applicable - No interns working or employed during inspection.

8) Are pharmacy support personnel working within their permitted scope?

Not Applicable - No support personnel working or employed during inspection.

5) * Filing and Storage of Prescriptions

2) Is the pharmacy maintaining non-controlled hard copy prescriptions electronically (i.e. scanned images)?

Yes - Compliant

Observation
For Information:
If yes, the pharmacy must comply with the following:

(1) All hard copy prescriptions for non-controlled dangerous drugs may be electronically filed and then destroyed after one hundred and eighty days from the date of creation or receipt.

(2) Disposal of the hard copy shall use a secure method of destruction to ensure privacy and confidentiality of the contents.

(3) All hard copy prescriptions electronically filed must be scanned front and back in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user. Prior to scanning, the written or faxed prescription shall be clearly notated to indicate it has been received by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

(4) The electronic form shows the exact and legible image of the original hard copy prescription.

OAC 4729:5-5-03 (E)

4) *Are all prescription records maintained for a period of three years?

Yes

Observation
The company retention policy is to keep records for a period of 10 years.

6) * Positive Identification

1) *Does the record keeping system capture the positive identification of the individual entering prescription information?

Yes

Observation
The software system is Enterprise RX. Positive ID is achieved via a unique username plus password and biometrics (fingerprint readers). Observed audit trail for patient PI (DOB: 2-24-1956) metformin prescription with no issues noted.

2) *Does the record keeping system capture the positive identification of the verification by the pharmacist of the prescription information entered into the record keeping system?

Yes

Observation
The software system is Enterprise RX. Positive ID is achieved via a unique username plus password and biometrics (fingerprint readers).

3) *Does the record keeping system capture the positive identification of the pharmacist conducting the prospective drug utilization review?

Yes

Observation
The software system is Enterprise RX. Positive ID is achieved via a unique username plus password and biometrics (fingerprint readers).

6) *Does the record keeping system capture the positive identification of the individual making any changes or annotations to a prescription?

Yes

Observation
The software system is Enterprise RX. Positive ID is achieved via a unique username plus password and biometrics (fingerprint readers).

7) Dispensing Records and Patient Profiles

1) Does the pharmacy maintain dispensing records containing the required information?

Yes

Observation
Observed dispensing records for patient PI (DOB: 2-24-1956) with no issues noted.
For Information:
Dispensing records must include the all the following:

(1) The original prescription number;
(2) Date of issuance of the original prescription order by the prescriber;
(3) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals;
(4) Residential address, including the physical street address and telephone number of the patient or owner;
(5) Full name and address of the prescriber, including the physical address of the prescriber's practice location;
(6) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription;
(7) Directions for use;
(8) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;
(9) The strength, dosage form, and quantity of the drug or device dispensed;
(10) The prescriber's federal drug enforcement administration number, if applicable;
(11) The positive identification of the persons performing specific actions pursuant to paragraph (A) of this rule;
(12) The total number of refills authorized by the prescriber;
(13) The date of dispensing;
(14) The refill history of the prescription, including all of the following:
(a) The prescription number;
(b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;
(c) The date(s) of dispensing; and
(d) The quantity dispensed.

OAC 4729:5-5-04 (C)

2) Does the pharmacy maintain dispensing records for the required time frame?

Yes

3) Does the pharmacy maintain patient profiles containing the required information?

Yes

Observation
Observed patient profile for patient PI (DOB: 2-24-1956) with no issues noted.
For Information:
Patient profiles consist of both a patient data record and a drug therapy record.

A patient data record shall contain all the following information:

(1) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals.

(2) Residential address, including the physical street address and telephone number of the patient or owner.

(3) Patient's date of birth.

(4) Patient's gender.

(5) A list of current patient-specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist:
(a) Drug related allergies;
(b) Previous drug reactions;
(c) History of or active chronic conditions or disease states; and
(d) Other drugs, including nonprescription drugs, devices, and nutritional supplements used on a routine basis.

(6) The pharmacist's comments relevant to the patient's drug therapy, including any other necessary information unique to the specific patient or drug.

A patient's drug therapy record shall contain all the following information for all prescriptions dispensed by the pharmacy within the last twelve months:

(1) The original prescription number.

(2) Date of issuance of the original prescription by the prescriber.

(3) Full name and address of the prescriber, including the physical address of the prescriber's practice location.

9) * General Record Keeping Requirements

1) *Does the pharmacy's record keeping system contain security features to prevent unauthorized access to the records?

Yes

Observation
The system requires a unique username and password plus biometrics for access, access is based on credentialing, and timeouts are in place. Octa Verify access is required for an employee's username and password to authenticate and access the system. Attempted to access the system with no success and observed RP access the system. No issues noted.

2) *Does the pharmacy's record keeping system contain back-up functionality to protect against record loss?

Yes

Observation
The system is backed-up in real time.

3) *Does the licensee maintain all DEA Forms 222 for a period of three years?

No

Observation
Category 2 license

4) *Does the pharmacy maintain required records outside of the confines of the pharmacy in accordance with Ohio rules?

No

Not Applicable - Pharmacy does not store records on-site outside of the actual pharmacy.

5) Does the licensee maintain records at an off-site location?

No

10) Drug Purchases

1) Does the licensee maintain complete and accurate records of drugs purchased?

Not Applicable - no drugs on-site

2) Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?

Not Applicable - no drugs on-site

11) * Security, Control, and Storage of Dangerous Drugs

1) Is a pharmacist providing supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs in the pharmacy?

Yes

2) Is the pharmacy separated from the merchandising or public areas?

No

Observation
This is a closed door pharmacy.

3) Are all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control?

Not Applicable

4) Are there any unauthorized persons present in the pharmacy?

No

5) *Are all schedule II controlled substances stored in a securely locked, substantially constructed cabinet or safe?

Not Applicable

Observation
Category 2 license

6) Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?

Not Applicable - not thiafentanil, carfentanil, etorphine hydrochloride, or diprenorphine on-site

7) *Can the pharmacy be secured by a physical barrier or alarm system?

Yes

Observation
The entity is located in a commercial office park. The building is a five story building of solid construction. The building is solely occupied by Elevance Health. Entrance to the building is via one entrance on the first floor. The entrance is equipped with 24/7 security personnel and a visitor pass is required for admittance. The entrance is under video surveillance.
The pharmacy is located within a suite on the 5th floor of the building. The suite is accessible via 3 entrances. All entrances are equipped with badge access. The back entrance is also equipped with a turn key back-up. Security holds the key. The suite is non-pharmacy barricade space.
Inside the suite, the pharmacy is secured and accessible via 2 entrances (solid wooden doors). Both entrances are secured with turn key locks and the keys are under the control of licensed pharmacists only. The walls and floors are solid. The exterior windows do not open and are equipped with dark shades. No issues noted.

8) *Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?

Yes

10) *Does the pharmacy have a secure area only accessible by pharmacists for customers to deposit new or refill prescription orders when the pharmacy is closed?

No - Not applicable

11) * Does the pharmacy maintain dangerous drugs or hypodermics outside of the confines of the pharmacy?

No

12) *Does the pharmacy provide services by means of a secured drive-through facility?

No

12) * Temperature Controls

1) *Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?

Not Applicable

Observation
No drug storage occurs on-site.

13) * Theft or Significant Loss of Drugs and Drug Documents

1) *Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

2) Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?

No

3) *REMINDER: Theft or significant loss of dangerous drugs and drug documents.

Observation
REMINDER

A licensee is required to report to the the Board and law enforcement authorities of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor.

A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

14) * Controlled Substance Inventory

1) *Does the licensee conduct an annual inventory of controlled substances?

Not Applicable

Observation
Category 2 license

2) How does the licensee monitor its inventory of controlled substances?

Observation
Category 2 license

15) * Drug Disposal

1) *Does the licensee dispose of controlled substances on-site using a method that renders the drug non-retrievable?

Not Applicable

3) Does the licensee maintain complete and accurate records of the disposal of controlled substances in accordance with Board rules?

Not Applicable

4) Does the licensee dispose of non-controlled drugs using a method that prevents the possession or use of the drugs by unauthorized persons?

Not Applicable

5) *Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs in accordance with Board rules?

Not Applicable

17) Drug Samples

1) Does the pharmacy have sample drugs as part its inventory?

No

19) Labeling

1) Are outpatient prescriptions labeled in accordance with Board rules?

No

Observation
No drug dispensing occurs from this site.

20) Patient Counseling

2) Additional Observations/Violations

Yes

Observation
Prescriptions are dispensed from the Arizona, Pennsylvania, or Illinois locations with written patient counseling information and an offer to counsel via phone. A phone call can be answered and counseling provided by a pharmacist at the Ohio location.

24) Repackaging

1) Does the pharmacy engage in the repackaging of dangerous drugs?

No

25) Customized Medication Packaging (Adherence Packaging)

1) Does the pharmacy dispense customized patient medication packages (sometimes referred to as adherence packaging)?

No

26) Partial Dispensing of Schedule II Controlled Substances

1) Does the pharmacy partially dispense schedule II controlled substances?

No

Observation
Category 2 license

27) Charitable Pharmacies

1) Is this pharmacy a charitable pharmacy?

No

28) * OARRS and Drug Utilization Review

1) *Are any of the Pharmacists using delegates to request OARRS reports?

No

2) Are pharmacists performing prospective drug utilization reviews prior to the dispensation of a prescription?

Yes

3) *REMINDER: OARRS reports cannot be provided directly to a patients or other health care professionals.

Observation
REMINDER: OARRS reports may be reviewed with the patient or another health care provider, however a copy may not be provided to the patient.

Patients requesting a copy of their OARRS report must submit a notarized request to the Board of Pharmacy in person or by mail, and the report must be received in person at the Board office during normal business hours. Proof of identity is required to obtain an OARRS report.

4) *REMINDER: Ohio law requires prescribers to obtain and review OARRS reports before initially prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient.

Observation
REMINDER: Rule 4729:5-5-08 requires a pharmacist to request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug to the patient's therapy that was not previously included;
(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;
(3) A prescriber is located outside the usual pharmacy geographic area;
(4) A patient is from outside the usual pharmacy geographic area;
(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;
(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance dangerous drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

For more information about these requirements, visit: www.pharmacy.ohio.gov/check

5) *REMINDER: A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Observation
Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

OAC 4729:5-5-08 (G)

29) Drug Compounding

1) Is the pharmacy engaged in either sterile or non-sterile drug compounding on site?

No

30) Naloxone Dispensing

1) Does the pharmacy dispense naloxone pursuant to a protocol?

No

31) * Expired/Adulterated Drugs

1) Are multi-dose vials properly labeled?

Not Applicable - No MDVs Present

2) *Are there expired/adulterated drugs present in the licensee's active drug stock?

Not Applicable

33) Prescription Pick-Up Station

1) Does the pharmacy accept prescriptions from pick-up stations or other intermediaries?

No

34) Immunization Administration - Ohio Requirements

1) Does the pharmacy offer immunizations in accordance with Ohio law?

No

35) Immunization Administration - Federal Requirements

1) Does the pharmacy offer immunizations in accordance with federal law?

No

39) Drug Repository Program

1) Does this pharmacy operate a drug repository program?

No

40) Temporary Removal of Drugs

1) Does the licensee engage in the temporary off-site storage of dangerous drugs?

No

41) Pharmacist Consult Agreements

1) Does the pharmacy have a consult agreement in place?

No

45) Dispensing Nicotine Replacement Therapy (NRT)

1) Does the licensee dispense NRT pursuant to a physician-approved protocol?

No

46) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient.

These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

49) Requested Records

1) Requested Records

Observation

The licensee is to produce, within three (3) business days (in a mutually acceptable format), any records requested to the State of Ohio Board of Pharmacy.

50) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Tyler Ingle, RPH

(signature)

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2025.

CarelonRx Pharmacy, Inc.

4241 Irwin Simpson Rd Ste 500

Mason, OH 45040-9011

License Number: 0234000029

Terminal - Pharmacy - LIMITED Category 2

Expiration Date: March 31, 2025

CLASS: Terminal - Pharmacy - LIMITED Category 2
BUSINESS TYPE: CRP – Contract Remote Order Entry

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
STEPHANIE ZAPPASODI ECKERT, RPH	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

eLicense Ohio
Professional Licensure

2762

License Look Up

12/4/2024 3:04 PM

CarelonRx Pharmacy, Inc.

License Number	0234000029
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - LIMITED Category 2
License Issue Date	03/30/2023
License Expiration Date	03/31/2025
License Effective Date	03/30/2023
Street Address	4241 Irwin Simpson Rd Ste 500
City	Mason
State	OH
Zipcode	45040-9011
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
STEPHANIE ECKERT	03230450	Active	Thu Jul 25 00:00:00 GMT 2024	

Current date & time: **12/4/2024 3:04 PM**

CarelonRx Pharmacy, Inc.

Tax ID # [redacted]

4821 North Stone Avenue

Suite C

Tucson, AZ 85704

Owners

CarelonRx Pharmacy, Inc

Tax ID# [redacted]

Executive Officers

Clayton Edwards – Vice President

Vincent Edward Scher – Treasurer

Kathleen Susan Kiefer – Secretary

Eric Kenneth Noble – Assistant Treasurer

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/2S/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: pending
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Go MD Pharmacy LLC

Physical Address: 3385 Airways Blvd. Ste. 217

City: Memphis State: TN Zip: 38116

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 901-654-1230 Toll Free # (NAC 639.708, NRS 639.23286): 833-805-0480

Fax: 888-818-3642 Contact Email: pharmacy@gomdpharmacy.net

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Akeylah Battle, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24377

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Akeylah Battle, PharmD	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: South Dakota

Parent Company (if any): _____

Corporation/Organization Name: GO MD Healthcare LLC

Mailing Address: 3385 Airways Blvd. Ste. 201

City: Memphis State: TN Zip: 38116

Telephone: 901-942-8283 Email: pharmacy@gomdpharmacy.net

Contact Person Name: Apollo Arcallana

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945).

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for GO MD Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Akeylah Battle, PharmD

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/4/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Akeylah Battle, Pharm D hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for GO MD Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 5 day of June, 2024

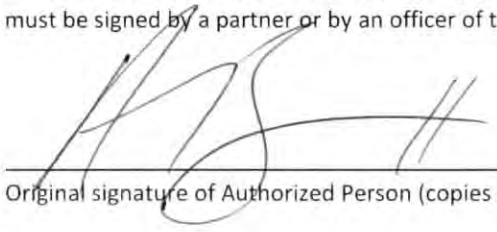
Ashley Merkling
Notary Public

ASHLEY MERKLING
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. FEB. 07, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Akeylah Battle, PharmD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

6/4/24

Date

Board Use Only	Date Received: 6/10/24	Amount: $500-ck 1020

State of South Dakota

Office of the Secretary of State

Certificate of Good Standing

Domestic Limited Liability Company

I, Monae L. Johnson, Secretary of State of the State of South Dakota, hereby certify that

GO MD PHARMACY LLC

Business ID: DL240843

was authorized to transact business in this state on: December 22, 2022.

I, further certify that **GO MD PHARMACY LLC** has complied with the laws of this State relative to the formation of Certificate of Good Standing/Authorizations of its kind and is now regularly and properly organized and existing under the laws of this State and is in Good Standing, as shown by the records of this office. This certificate is not to be construed as an endorsement, recommendation or notice of approval of its financial condition or business activities and practices. Such information is not available from this office.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of South Dakota, in Pierre, the Capital City, this day, June 2, 2024.

Monae L. Johnson

Monae L. Johnson
Secretary of State

06/02/2024 10:13 PM

Verification #: 017715420

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: GD MD PHARMACY	
STREET: 3385 AIRWAYS BLVD STE 217	
CITY: MEMPHIS	ZIP: 38116
DATE OPENED:	TELEPHONE NO.: (901) 942-8283
LICENSE NO.: N/A	EXPIRY DATE: N/A
DEA NO.: N/A	EXPIRY DATE: N/A
PHARMACIST IN CHARGE/Duty: Aleylah Battle	LIC NO.: 39858 / EXPIRY DATE: 10/31/25

Inspected by	Date
DEREK JOHNSTON	5/10/24

This Inspection Satisfactory: Yes ☐ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
	✓	1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
N/A		14. Shelves and drug stock clean
✓		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Compliance Yes	Compliance No		
		19. RXs numerically filed	
✓	✓	☐ All C's together ☐ C-11's separate ☐ Multiple file method	
✓		20. Patients identifiable	
✓		21. Prescribers identifiable	
✓		22. New verbal RXs initialed by appropriate personnel	
✓		23. Date of original dispensing	
✓		24. Initials of dispensing D.Ph.	
✓		25. Quantity dispensed indicated	
✓		26. Appropriate Emergency C-11 RXs	
✓		27. Computer labels applied appropriately to RXs	
✓		28. Pharmacist Signature Log	
✓		29. Daily Print Out	

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
		37. All C-11 records separate
✓		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
✓		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date)
		42. Last Theft/loss report (date)
		43. Access to Control Substance Monitoring Database

Pharmacy Hours: 10-6 M-F 8-4 SAT

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☑

Immediately							
Needs Improvement							
Within 30 Days							

Remarks or Recommendations:

I _____ hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

2772

Completed Internet Form - NOT FOR SUBMISSION **DEA/Control Number:** W24069856A **Submission Date:** Fri May 31 14:56:37 EDT 2024	**APPLICATION FOR REGISTRATIONUNDER CONTROLLED SUBSTANCES ACT OF 1970**	**Form** DEA 224 Completed Internet Receipt. NOT FOR SUBMISSION
NAME: Applicant or Business (LAST) GO MD PHARMACY	**(First, MI)**	Application Complete. Tracking Number: Fee Paid: 888
TAX IDENTIFYING NUMBER and/or XX-XXXXX72	**SOCIAL SECURITY NUMBER**	For more information regarding SSN/TIN, See Note 3 under ADDITIONAL INFORMATION below
PROPOSED BUSINESS ADDRESS. (When entering a P.O. box, you are required to enter a street address) 3385 AIRWAYS BLVD. STE. 217		

CITY MEMPHIS	**STATE** TN **ZIP CODE** 38116
APPLICANT'S BUSINESS PHONE NUMBER 9016541230	**POC CELL PHONE NUMBER** 9018284495
POC NAME AKEYLAH BATTLE	**POC EMAIL ADDRESS** PHARMACY@GOMDPHARMACY.NET

REGISTRATION CLASSIFICATION

BUSINESS ACTIVITY: RETAIL PHARMACY	**INDICATE HERE IF YOU REQUIRE ORDER FORMS.** Y

Drug Schedules: 2 2N 3 3N 4 5

State License/Liability Information

You must be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate.
Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn **WITHOUT refund.**

State License No. 7780	State: TN	Expire Date: 05-31-2026
State Controlled License No.		Expire Date:

1. Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or any such action pending?	N
2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?	N
3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?	N
4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?	N

Registration Fee: Registration Fee Paid: 888

Certification for Fee Exemption (if applicable)

Certifying Official's Name		**Certifying Official's Title**	
Certifying Official's Phone		**Certifying Official's Email**	
Name of Fee Exempt Institution			

Practitioner Information (if applicable)

National Provider ID		**Professional Degree**	
Date of Birth		**Graduation Year (Medical/Professional School)**	
Medical/Professional School			

Manufacturer Details (if applicable)

Category/Schedule	1	2	2N	3	3N	4	5	L1
Bulk, Synthesizer - Extractor								
Dosage Form								
Repacker - Relabeler								
Non-Human Consumption								

Application Certification:

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.

By typing my full name in the space below, I hereby certify that the foregoing information furnished on this electronic DEA application is true and correct and understand that this constitutes an electronic signature for purposes of this electronic DEA application only.

* Name of Applicant (For individual registrants, the registrant themselves MUST complete this E-Signature) or name of Officer of the Corporation/Company

e-Signature: AKEYLAH BATTLE, PHARMD

This electronic DEA application must be certified by the applicant/registrant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust, or other entity. See 21 C.F.R § 1301.13(j) for more information on who can certify this application

ADDITIONAL INFORMATION

Form 224 Form 224 ApprovedOMB Form No. 1117-0014 Expires: 06/30/2026(12 minutes)

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is (See Above). Public reporting burden for this collection of information is estimated to average (See Above) per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.
3. The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.
4. **PRIVACY ACT NOTICE:**
   Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are §§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§ 822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and person registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

Last Updated: 5/31/2024

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

2775

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy
County = SHELBY
Results = 1

Click here to return to the search page

1	GO MD PHARMACY LLC 3385 AIRWAYS BLVD STE 217 Memphis, TN 38116 901-942-8283 *Qualifications* *Controlled Subs*	Pharmacist: BATTLE, AKEYLAH Facility License Number: 00007780 Status: Licensed Date of Original Licensure: 05/29/2024 Date of Expiration: 05/31/2026 **No Disciplinary Actions**

GO MD PHARMACY LLC
3385 Airways Blvd Ste 217
Memphis, TN 38116
901-654-1230

Dear Pharmacy Board,

We are writing to inform you that we cannot provide a copy of our DEA permit yet as it has not yet been issued. We have, however, filed for it. Attached is a copy of the filing receipt, so we request an exemption to the requirement to provide this as we have no control over when the DEA permit will be issued.

Best Regards,

Apollo Arcallana

Apollo Arcallana
GO MD PHARMACY LLC
President

GO MD PHARMACY LLC Organizational Chart

Easy Scripts Inc
(Publicly Traded NV Corporation)

↓

GO MD HEALTHCARE LLC
(SD Limited Liability Company, Subsidiary of Easy Scripts Inc)

↓

GO MD PHARMACY LLC
(SD Limited Liability Company)

GO MD HEALTHCARE LLC Organizational Chart

Easy Scripts Inc
(Publicly Traded NV Corporation)

↓

GO MD HEALTHCARE LLC
(SD Limited Liability Company, Funding GO MD PHARMACY LLC)

↓

GO MD PHARMACY LLC
(SD Limited Liability Company)

Key Details:

- Easy Scripts Inc: A publicly traded Nevada Corporation that has filed for suspension of reporting requirements in 2009.
- GO MD HEALTHCARE LLC: A South Dakota LLC, subsidiary of Easy Scripts Inc.
- GO MD HEALTHCARE LLC: A South Dakota LLC, funding GO MD PHARMACY LLC 100%.
- GO MD PHARMACY LLC: A South Dakota LLC, subsidiary of GO MD HEALTHCARE LLC, operating as its own entity.
- Apollo Arcallana: President of all companies and sole managing officer for all entities.

SEC Reporting Requirements:

As per SEC regulations, Easy Scripts Inc has filed for suspension of reporting requirements in 2009. This means the company is no longer required to file Form 10-K until it opts to notify the SEC to resume reporting. This suspension is in compliance with SEC rules allowing publicly traded companies to terminate reporting obligations under certain conditions.

Termination of Reporting Requirement Document:

For the board's request, provide a copy of the termination of reporting requirements for Easy Scripts Inc to demonstrate the current status.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 15

CERTIFICATION AND NOTICE OF TERMINATION OF REGISTRATION UNDER SECTION 12 (g) OF THE SECURITIES EXCHANGE ACT OF 1934 OR SUSPENSION OF DUTY TO FILE REPORTS UNDER SECTIONS 13 AND 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

Commission File Number: 000-53292

EASY SCRIPTS INC.
(Exact name of registrant as specified in its charter)

701 N. Green Valley Parkway Suite 200
Henderson, NV 89074
(Address of principal executive offices and Zip Code)

(877) 269-4984
(Registrant's telephone number, including area code)

Common Stock, Par Value $0.0001
(Title of each class of securities covered by this Form)

None
(Titles of all other classes of securities for which a duty to file reports under section 13(a) or 15(d) remains)

Please place an X in the box(es) to designate the appropriate rule provision(s) relied upon to terminate or suspend the duty to file reports:

Rule 12g-4(a)(1) [X]
Rule 12g-4(a)(2) [ ]
Rule 12h-3(b)(1)(i) [ ]
Rule 12h-3(b)(1)(ii) [ ]
Rule 15d-6 [ ]

Approximate number of holders of record as of the certification or notice date: 31

Pursuant to the requirements of the Securities Exchange Act of 1934, EASY SCRIPTS, INC., has caused this certification/notice to be signed on its behalf by the undersigned duly authorized person.

Date: June 29, 2010

By: /s/ Kendra Marcoux
President, Director, Treasurer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Quarterly Report under Section 13 or 15(d) of
The Securities Exchange Act of 1934

For the Quarterly Period ended September 30, 2009

Commission File Number 333-138332

EASY SCRIPTS, INC.

(Name of registrant in its charter)

NEVADA
(State or other jurisdiction of incorporation or organization)

701 N. Green Valley Parkway Suite 200
Henderson, NV 89074
(Address of principal executive offices and Zip Code)

(877) 269-4984
(Registrant's telephone number, including area code)

Copy of Communication to:
Befumo & Schaeffer, PLLC
2020 Pennsylvania Ave., NW # 840
Washington, DC 20006

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15 (d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes [ ] No [ ] Not required

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Go MD Pharmacy llc

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 3385 Airways Blvd. Ste 217

City: Memphis State: TN Zip: 38116

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 901-654-1230 Website: Gomdusa.com/landingpage

Licensing Company Email: pharmacy@gomdpharmacy.net

Section 2: Personal Information

First: Akeylah Middle: Last: Battle

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Cordova State: TN Zip: 38116

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Tennessee Health Science Center		09/08 - 05/12	
Address	**City**	**State**	**Zip**
881 Madison Ave.	Memphis	TN	38163
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Tennessee		08/04 - 05/08	
Address	**City**	**State**	**Zip**
1331 Circle Park Dr.	Knoxville	TN	37916
Diploma/Degree obtained, if any			
BS: Biochemistry Cellular & Molecular Biology			

School Name		From - To (MM/YY – MM/YY)	
White Station High School		08/00 - 05/04	
Address	**City**	**State**	**Zip**
514 S. Perkins Rd.	Memphis	TN	38117
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/22 - current	[redacted]	Cordova	TN	38018
09/19 - 11/22		Houston	TX	77079
07/17 - 09/19		Houston	TX	77005
05/16 - 07/17		Houston	TX	77098
04/14 - 05/16		Houston	TX	77098
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Go MD Pharmacy LLC			05/24 - current	
Business Address		**City**	**State**	**Zip**
3385 Airways Blvd. Ste 217		Memphis	TN	38116
Phone	**Title**		**Number of Employed Hours**	
901-654-1230	Pharmacist in Charge		600	
Description of Duties				
Perform daily management of pharmacy, supervising all aspects of operation in absence of owner. Maintain drug inventory by ordering necessary medications and supplies, and verifying deliveries against orders.				

Business Name			From - To (MM/YY – MM/YY)	
S & K Med Pharmacy			10/13 - 6/22	
Business Address		**City**	**State**	**Zip**
1396 Eldridge Pkwy Ste. D		Houston	TX	77077
Phone	**Title**		**Number of Employed Hours**	
281-752-7244	Pharmacist in Charge		18,000	
Description of Duties				
Perform daily management of pharmacy, supervising all aspects of operation in absence of owner. Maintain drug inventory, customer service, staff training etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Akeylah Battle, PharmD, certify that as the designated representative for

Go MD Pharmacy llc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. A.B. I am at least 21 years of age;
3. A.B. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. A.B. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. A.B. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. A.B. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. A.B. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Akeylah, Battle
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/04/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Akeylah, Battle

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/04/24

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Akeylah Battle, Pharm D, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/4/24

Date

Subscribed and Sworn to before me this 4 day of November

Notary Public Signature

GAVIN STONE
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. MAY 02, 2028
(Seal)

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	☐ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	■ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	■ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties

Physical Address: 625 S Pear Orchard Rd, Ste A

City: Ridgeland State: MS Zip: 39157

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 769-233-8484 Toll Free # (NAC 639.708, NRS 639.23286): 1-844-766-0464

Fax: 769-233-8051 Contact Email: pharmacy@hcmedinfusion.biz

Website: healthcaremedicalinfusion.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Christy Neely, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~NA~~ 24403

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christy Neely, PharmD	NV Pharmacist Registration #: 24403
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Mississippi

Parent Company (if any): _____

Corporation/Organization Name: Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties

Mailing Address: 625 S Pear Orchard Rd, Ste A

City: Ridgeland State: MS Zip: 39157

Telephone: 769-233-8484 Email: pharmacy@hcmedinfusion.biz

Contact Person Name: Christy Neely, PharmD

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Preston Tolley

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

08/20/2024
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Preston Tolley hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Preston Tolley

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of February, 2024

Kristel Young Walker

Notary Public

STATE OF MISSISSIPPI
KRISTEL YOUNG WALKER
NOTARY PUBLIC
Madison County
Commission Expires
April 10, 2026
COMMISSION NUMBER 214485

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Preston Tolley, President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

03/20/2024
Date

Board Use Only	Date Received: 3/4/24	Amount: $500-check 23057

Michael Watson
SECRETARY OF STATE

Office of the Secretary of State
Jackson, Mississippi

Certificate of Good Standing

I, MICHAEL WATSON, Secretary of State of the State of Mississippi, and as such, the legal custodian of the records as required by the laws of Mississippi, to be filed in my office, do hereby certify:

That on the 30th day of June, 2005, the State of Mississippi issued a Charter/ Certificate of Authority to:

ADVANCED MEDICAL, INC.

That the state of incorporation is Mississippi.

That the period of duration is perpetual.

That according to the records of this office, Articles of Dissolution or a Certificate of Withdrawal have not been filed.

That according to the records of this office, a current Annual Report has been delivered to the Office of the Secretary of State.

I further certify that all fees, taxes and penalties owed to this state, as reflected in the records of the Secretary of State, have been paid and that the corporation is in existence or has authority to transact business in Mississippi.

That insofar as the records of this office are concerned, the said Advanced Medical, Inc. is in good standing at this time.

Given under my hand and seal of office
the 20th day of February, 2024

Michael Watson

Certificate Number: CN24182611
Verify this certificate online at http://corp.sos.ms.gov/corpconv/verifycertificate.aspx

Mississippi Board of Pharmacy

Inspection Details

Name	Permit #	DEA #:	Assigned To
Advanced Medical, Inc.	18519 [2.0]	**DEA Expiration:**	
DBA	**CS #**	**Inspection Date**	
Health Care Medical Infusion Specialties	CS-19854 - 05/02/2023 (Open)	12/14/2023	
Address	**Compounding #**	**Inspection User**	
625 S Pear Orchard Rd Ste A Ridgeland, MS 39157 Madison	**Pharmacist In Charge** Leann R. Williams	Ramsey, James	

Comments

None

Community

	Answer	Question
1)	Satisfactory	Pharmacist on duty.
2)	Satisfactory	Pharmacy clean and orderly.
3)	Satisfactory	Prescriptions being properly filed. (Article XIII) (Any RX not maintained in a paper file must be printed and provided to an agent immediately)
4)	Not Applicable	Outdated drugs in stock.
5)	Not Applicable	Handling of outdated CS.
6)	Not Applicable	Adequate security of CS.
7)	Satisfactory	CS inventoried properly.
8)	Not Applicable	Ordering/Receiving CII drugs.
9)	Not Applicable	CS prescriptions filled properly.
10)	Not Applicable	Dates on CS Prescriptions.
11)	Not Applicable	Addresses on CS Prescriptions.
12)	Not Applicable	Initials on CS Prescriptions.
13)	Not Applicable	DEA number on CS prescriptions.
14)	Satisfactory	Pharmacy only utilizes suppliers permitted by the Board.
		Comments: Smith Drug
15)	Not Applicable	Pharmacy only utilizes Reverse Distributors permitted by the Board.
16)	Not Applicable	Does the pharmacy provide medications to other pharmacies, physicians or facilities (such as an IEMK)? (Review invoices)
17)	Not Applicable	CS Invoice filed/retrievable.

Community

	Answer	Question
18)	Not Applicable	CS hard copy printout.
19)	Satisfactory	Patient counseling.
20)	Not Applicable	Schedule V OTC sales.
21)	Satisfactory	Dispensed Rx labeling.
22)	Not Applicable	Technician compliance. (Ratio 3:1, Training/Certification)
23)	Not Applicable	Sterile compounding.

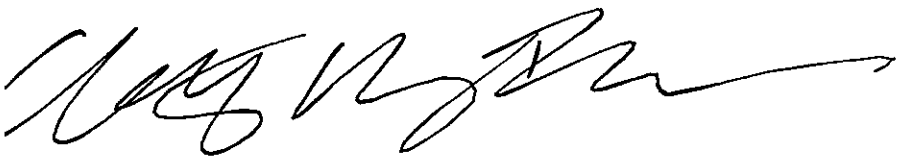
Comments: Have not compounded anything to date.

24)	Not Applicable	Non-Sterile compounding.

Person Providing Information

Full Name:
Christy Neely

Signature:



MISSISSIPPI BOARD OF PHARMACY

6311 Ridgewood Rd, Ste E401 Jackson, MS 39211 39211-2038/TELE: 601-899-8880/FAX: 601-899-8851

February 23, 2024

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy
Ste 206
Reno, NV 89521

STATE OF MISSISSIPPI
COUNTY OF HINDS

RE: CERTIFICATION OF RESIDENT PHARMACY PERMIT

ADVANCED MEDICAL INC DBA: HEALTH CARE MEDICAL INFUSION SPECIALTIES
Issuance- February 17, 2023
License Number-18519/2.0
625 S Pear Orchard Rd., Ste A
Ridgeland, MS 39157

I, Merrill Garner, Licensing Professional of the Mississippi Board of Pharmacy, certify that as official custodian of the records of the Board and pursuant to a request, do hereby certify that Advanced Medical, Inc. dba: Health Care Medical Infusion Specialties is currently licensed and in active status with an expiration date of December 31, 2025. There has not been any disciplinary action taken against this permit.

Witness my signature and the seal of the Mississippi Board of Pharmacy this the 23rd day of February 2024.

Merrill Garner

Merrill Garner, Licensing Professional
Mississippi Board of Pharmacy

2798

MISSISSIPPI

Board of Pharmacy

Permit #
18519 / 2.0

Pharmacy

Specialty Community - Combination

Advanced Medical, Inc.

DBA Health Care Medical Infusion Specialties

625 S Pear Orchard Rd Ste A
Ridgeland, MS 39157
Madison

Permit Holder:
Christy L. Neely

This permit is not transferable or assignable.

Issued: 02/17/2023
Renewed: 02/14/2024
Expires: 12/31/2025

Susan McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties

Pharmacy/Wholesaler License # (if applicable): 18519/2.0

Physical Address: 625 S Pear Orchard Rd, Ste A

City: Ridgeland State: MS Zip: 39157

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 769-233-8484 Website: healthcaremedicalinfusion.com

Licensing Company Email: pharmacy@hcmedinfusion.biz

Section 2: Personal Information

First: Christy Middle: Lynn Last: Neely

Alias(es, nicknames, name changes, etc.): Christy Lynn Burnham

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Brandon State: Zip:

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	n/a	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		2000-2002	
Address	**City**	**State**	**Zip**
School of Pharmacy	University	MS	38677
Diploma/Degree obtained, if any: Pharm D			

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		1996-2000	
Address	**City**	**State**	**Zip**
School of Pharmacy	University	MS	38677
Diploma/Degree obtained, if any: BS Pharmaceutical Sciences			

School Name		From - To (MM/YY – MM/YY)	
Florence High School		1992-1996	
Address	**City**	**State**	**Zip**
23 Hwy 469 N	Florence	MS	39073
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2010 to currently	[redacted]	Brandon	MS	39042
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties			2/14/2024 - currently
Business Address	**City**	**State**	**Zip**
625 S Pear Orchard Rd, Ste A	Ridgeland	MS	39157
Phone	**Title**	**Number of Employed Hours**	
769-233-8484	PIC	40 hrs/wk	
Description of Duties			
dispensing prescriptions, following rules and regulations of MS BOP to keep records of prescriptions dispensed, invoices, inventory etc, clinically monitor patients, overseeing purchasing and billing			

Business Name			From - To (MM/YY – MM/YY)
Health Care Medical Infusion Specialties			5/2017 - 2/14/2024
Business Address	**City**	**State**	**Zip**
625 S Pear Orchard	Ridgeland	MS	39157
Phone	**Title**	**Number of Employed Hours**	
601-420-0064	PIC	40 hrs/wk	
Description of Duties			
dispensing prescriptions, following rules and regulations of MS BOP to keep records of prescriptions dispensed, invoices, inventory etc, clinically monitor patients, overseeing purchasing and billing			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Christy Neely, **certify that as the designated representative for**

Advanced Medical, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christy Neely

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/21/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christy Neely
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/21/24
Date

Please have this section completed in the presence of a Notary Public.

State of Mississippi, ss. County of Madison

I, Christy Neely, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/21/24
Date

Subscribed and Sworn to before me this 21st day of February, 2024

Notary Public Signature

STATE OF MISSISSIPPI
KRISTEL YOUNG WALKER
NOTARY PUBLIC
Madison County
Commission Expires
April 10, 2026
COMMISSION NUMBER 314456

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advanced Medical, Inc. DBA Health Care Medical Infusion Specialties

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 18519/2.0 MS

Physical Address: 625 S Pear Orchard Rd, Ste A

City: Ridgeland State: MS Zip: 39157

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 769-233-8484 Website: healthcaremedicalinfusion.com

Licensing Company Email: pharmacy@hcmedinfusion.biz

Section 2: Personal Information

First: Preston Middle: Fairfax Last: Tolley

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Madison State: MS Zip: 39110

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	n/a	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Oklahoma State University		2003	
Address	City	State	Zip
	Tulsa	OK	
Diploma/Degree obtained, if any			
Certified Pedorthist			
School Name		From - To (MM/YY – MM/YY)	
Hinds Community Colege		1999-2001	
Address	City	State	Zip
	Raymond	MS	
Diploma/Degree obtained, if any			
Associates Degree- Information Technology			
School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		1975-1977	
Address	City	State	Zip
	Oxford	MS	
Diploma/Degree obtained, if any			
General Studies			
School Name		From - To (MM/YY – MM/YY)	
Southeastern Louisiana University		1972-1975	
Address	City	State	Zip
	Hammond	LA	
Diploma/Degree obtained, if any			
none			
School Name		From - To (MM/YY – MM/YY	
Jackson Prep		1971-1972	
Address	City	State	Zip
	Jackson	MS	
Diploma/Degree obtained, if any			
highschool diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2005-currently	[redacted]	Madison	MS	39110
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Advanced Medical			2005 - currently
Business Address	**City**	**State**	**Zip**
625 S Pear Orchard, Ste A	Ridgeland	MS	39157
Phone	**Title**		
769-233-8484	President		
Description of Duties			
President			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	n/a	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Preston Tolley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Mississippi, ss. County of Madison

I, Preston Tolley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/20/2024

Date

Subscribed and Sworn to before me this 20th day of February 2024

Notary Public Signature

STATE OF MISSISSIPPI
KRISTEL YOUNG WALKER
NOTARY PUBLIC
Madison County
Commission Expires
April 10, 2026
COMMISSION NUMBER 314456

(Seal)

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FL4660610
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: LifeMD Pharmacy Services, LLC

Physical Address: 499 Running Pump Rd. Ste. 106

City: Lancaster State: PA Zip: 17601

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-501-2975 Toll Free # (NAC 639.708, NRS 639.23286): 800-501-2975

Fax: 717-902-5382 Contact Email: licensing@lifemdpharmacy.com

Website: None

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Adam Womack

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22825

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Adam Womack	NV Pharmacist Registration #: 22825
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a <u>signed statement of explanation must be attached</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): LFMD Pharmacy Holdings 1, LLC

Corporation/Organization Name: LifeMD Pharmacy Services, LLC

Mailing Address: 499 Running Pump Rd. Ste. 106

City: Lancaster State: PA Zip: 17601

Telephone: 800-501-2975 Email: licensing@lifemdpharmacy.com

Contact Person Name: Adam Womack

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist In Charge (title) for LifeMD Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Adam Womack
Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/1/24
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adam Womack hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (title) for LifeMD Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 4 day of November, 2024

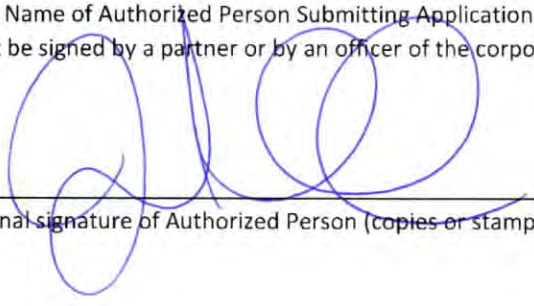
Notary Public

Commonwealth of Pennsylvania – Notary Seal
John Dennis Ring, Notary Public
Lancaster County
My commission expires March 15, 2025
Commission number 1391158

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Schreiber

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

11/4/24

Date

Board Use Only	Date Received: 11/12/24	Amount: $500-CK 6802701515

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LFMD PHARMACY HOLDINGS 1, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LFMD PHARMACY HOLDINGS 1, LLC" WAS FORMED ON THE TWENTY-THIRD DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

3749494 8300

SR# 20243714534

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204460590

Date: 09-23-24

STATE OF DELAWARE

CERTIFICATE OF FORMATION

OF

LFMD PHARMACY HOLDINGS 1, LLC

The undersigned, being an authorized person, for the purpose of forming a limited liability company under the Delaware Limited Liability Company Act, Chapter 18, Title 6, Delaware Code, Section 18-101 et seq (the "Act"), hereby certifies pursuant to Section 18-201 (a) of the Act, that:

1. The name of the limited liability company is LFMD Pharmacy Holdings 1, LLC.

2. The address of the Corporation's registered office in the State of Delaware is 251 Little Falls Drive, Wilmington, New Castle County, DE 19808. The name of its registered agent at such address is Corporation Service Company.

3. This Certificate of Formation shall be effective upon filing.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation as of this 22nd day of May 2024.

DocuSigned by:
/s/
Name: Shayna Dray
Authorized Person

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:23 PM 05/23/2024
FILED 12:23 PM 05/23/2024
SR 20242393141 - File Number 3749494

2818

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

LIFEMD PHARMACY SERVICES, LLC

499 RUNNING PUMP RD. STE. 106
LANCASTER, PA, 17601

Phone: 800-501-2975
Owner: ADAM WOMACK

LICENSE

License No: AA0005456161
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business
Inspection Date: 08/20/2024 •
Inspection Result: Passed •

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

ALLEN SOLOMON	8/20/2024 10:22:05 AM	Adam Womack - RP456348
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

LIFEMD PHARMACY SERVICES, LLC

499 RUNNING PUMP RD. STE. 106
LANCASTER, PA, 17601

Phone: 800-501-2975
Owner: ADAM WOMACK

LICENSE

License No: AA0005456161
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 08/20/2024
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	YES
Is the automated medication systems properly validated?	YES
Are there policies and procedures for the operation of the automated medication systems?	YES
Is there a program for quality assurance for the automated medication systems?	YES
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Commonwealth of Pennsylvania- Department of State
Bureau of Professional and Occupational Affairs

Mailing Address P.O. Box 2649, Harrisburg, PA 17105 Toll Free: 1-833-DOS-BPOA

LIFEMD PHARMACY SERVICES, LLC
ADAM WOMACK

License Number	: PP483193	Initial License Date : 08/20/2024	Expiration Date : 08/31/2025
License Type	: Pharmacy		License Status as of 8/21/2024 : Active
Issued By	: State Board of Pharmacy		
Address	: 499 RUNNING PUMP RD. STE. 106, LANCASTER, PA 17601		

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature of Licensee

SCAN ME

Please verify the license by visiting https://www.pals.pa.gov/verify or by scanning the QR Code

20240820559

2821

LifeMD Pharmacy Services

LFMD Pharmacy Holdings 1, LLC Officers

Title	President
Name	Justin Schreiber
Home Address	[redacted] Lancaster, PA 17603
Telephone Number	[redacted]

Title	Secretary
Name	Shane Biffar
Home Address	[redacted] Pelham, NY 10803
Telephone Number	[redacted]

Title	Treasurer
Name	Marc Benathen
Home Address	[redacted], New York, NY 10065
Telephone Number	[redacted]

LifeMD Pharmacy Services

LifeMD Pharmacy Services, LLC Officers

Title	President
Name	Justin Schreiber
Date of Birth	[redacted]
Business Address	236 5th Avenue Suite 400, 4th Floor New York, NY 10001
Telephone Number	[redacted]

Title	Secretary
Name	Shane Biffar
Date of Birth	[redacted]
Business Address	236 5th Avenue Suite 400, 4th Floor New York, NY 10001
Telephone Number	[redacted]

Title	Treasurer
Name	Marc Benathen
Date of Birth	[redacted]
Business Address	236 5th Avenue Suite 400, 4th Floor New York, NY 10001
Telephone Number	[redacted]

LifeMD Pharmacy Services

LifeMD Pharmacy Services, LLC Org Chart

Name	**LifeMD, Inc**
EIN	[redacted]
Address	236 Fifth Avenue, Suite 400, New York, NY 10001
Phone Number	866-351-5907

↓100% Ownership

Name	**LFMD Pharmacy Holdings, LLC**
EIN	[redacted]
Address	236 Fifth Avenue, Suite 400, New York, NY 10001
Phone Number	866-351-5907

↓100% Ownership

Name	**LFMD Pharmacy Holdings 1, LLC**
EIN	[redacted]
Address	236 Fifth Avenue, Suite 400, New York, NY 10001
Phone Number	866-351-5907

↓100% Ownership

Name	**LifeMD Pharmacy Services, LLC**
EIN	[redacted]
Address	499 Running Pump Rd Ste 106, Lancaster, PA 17601
Phone Number	800-501-2975

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LifeMD Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 499 Running Pump Rd Ste 106

City Lancaster State PA Zip 17601

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-501-2975 Website None Yet

Licensing Company Email licensing@lifemdpharmacy.com

Section 2: Personal Information

First Adam Middle Lee Last Womack

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Elizabethtown State PA Zip 17022

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University College of Pharmacy - Glendale		05/2011-05/2014	
Address	**City**	**State**	**Zip**
19555 N 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
Doctor of Pharmacy (Pharm.D.)			

School Name		From - To (MM/YY – MM/YY)	
University of Arizona		05/2005-05/2009	
Address	**City**	**State**	**Zip**
1200 E University Blvd	Tucson	AZ	85721
Diploma/Degree obtained, if any			
Bachelor of Science in Nutritional Sciences			

School Name		From - To (MM/YY – MM/YY)	
Cienega High School		05/2001-05/2005	
Address	**City**	**State**	**Zip**
12775 E Mary Ann Cleveland Way	Vail	AZ	85641
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2021-Present	[redacted]	Elizabethtown	PA	17022
11/2017-11/2021	[redacted]	Phoenix	AZ	85053
01/2014-11/2017	[redacted]	Glendale	AZ	85308
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Covetrus North America, LLC			09/2021-04/2024	
Business Address		City	State	Zip
1499 Zeager Rd Ste 5		Elizabethtown	PA	17022
Phone	Title		Number of Employed Hours	
Pharmacy is Closed	Pharmacist In Charge		5580	
Description of Duties				
Regulatory compliance. Creating and modifying SOPs. Maintaining licensure. Filling and shipping prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
Covetrus North America, LLC			02/2015-09/2021	
Business Address		City	State	Zip
2401 W Grandview Rd Phoenix		Phoenix	AZ	85023
Phone	Title		Number of Employed Hours	
(877) 518-4589	Non-Sterile Compounding Manager		15,800	
Description of Duties				
Regulatory compliance for Non-Sterile Compounding. Maintenance of SOPs. Management and scheduling of a large team.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Adam Womack, **certify that as the designated representative for**

LifeMD Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ALW I am at least 21 years of age;
3. ALW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ALW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ALW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ALW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ALW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Adam Womack

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/7/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adam Womack

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/7/24

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Lancaster

I, Adam Womack, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

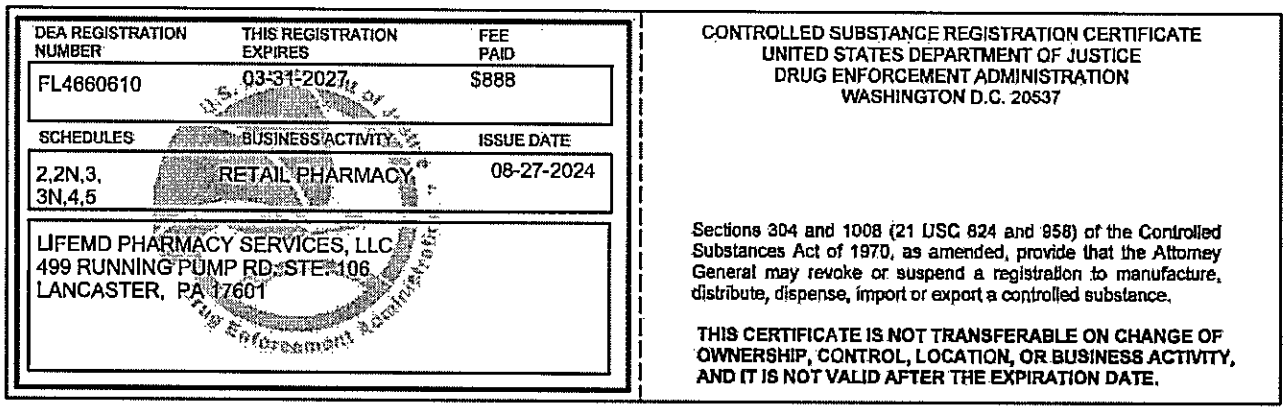
Date 11/7/24

Subscribed and Sworn to before me this 7 day of November 2024

Notary Public Signature

Commonwealth of Pennsylvania – Notary Seal
Trina M. Albert, Notary Public
City of Lancaster, Lancaster County
My Commission Expires December 2, 2026
Commission Number 1001192

(Seal)



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FL4660610	03-31-2027	$888

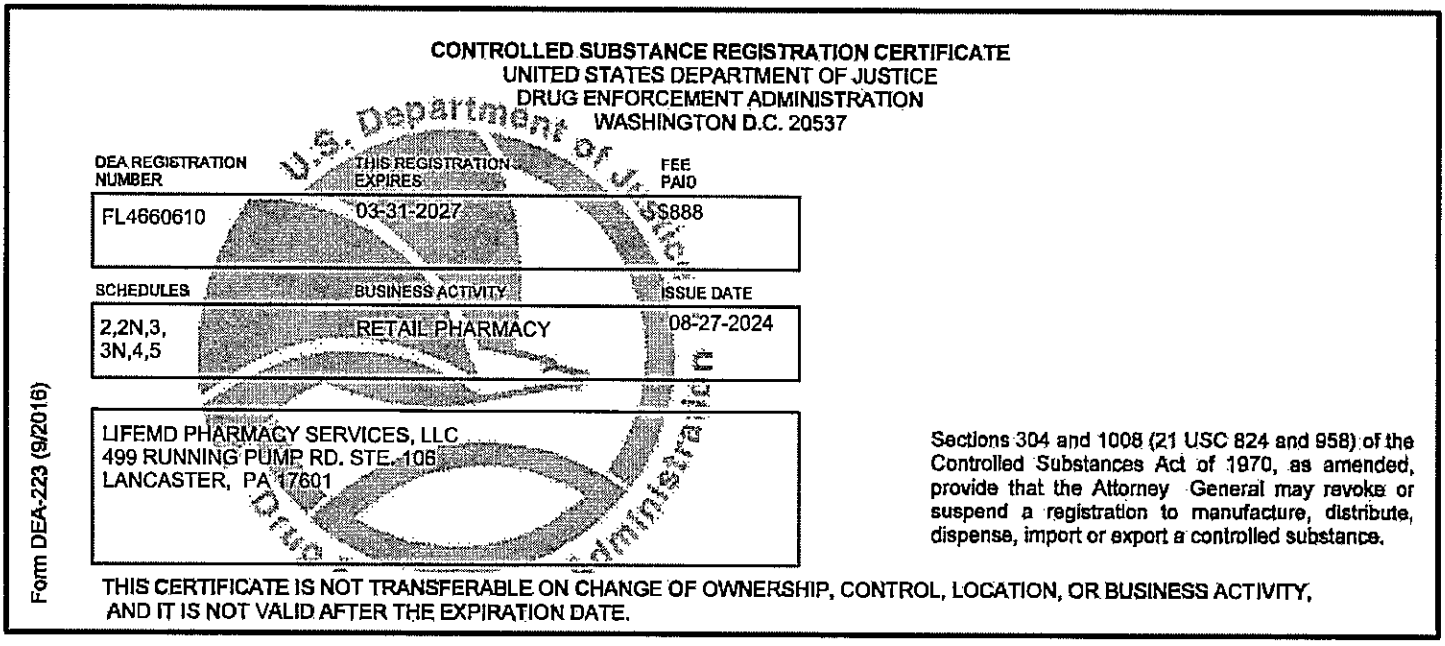
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-27-2024

LIFEMD PHARMACY SERVICES, LLC
499 RUNNING PUMP RD. STE. 106
LANCASTER, PA 17601

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FL4660610	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-27-2024

LIFEMD PHARMACY SERVICES, LLC
499 RUNNING PUMP RD. STE. 106
LANCASTER, PA 17601

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Form DEA-223 (9/2016)

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change* ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) *Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FN0830996 ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: NPS Pharmacy Direct

Physical Address: 442 Metroplex Drive, STE 401

City: Nashville State: TN Zip: 37211

Mailing Address (if different from physical address): PO Box 157

City: Brentwood State: TN Zip: 37024

Telephone: 615-724-0924 Toll Free # (NAC 639.708, NRS 639.23286): 615-724-0924

Fax: _____ Contact Email: compliance@npspharmacy.com

Website: www.npspharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Aaron Logan Smith, TN license 38383

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Lindsey Warren, NV License 23955

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Lindsey Warren	NV Pharmacist Registration #: 23955
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✔	

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Kevin Hartman

Business Name: NPS Pharmacy Direct

Business Address: 442 Metroplex Dr, Ste 401

City: Nashville State: TN Zip: 37211

Telephone: 615-724-0924 Email: compliance@npspharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO and Founder (title) for NPS Pharmacy Direct (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kevin Hartman

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/5/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Aaron Logan Smith hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for NPS Pharmacy Direct (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Aaron Logan Smith
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12th day of April, 20 24

Brandy Hunter
Notary Public

Brandy Hunter
STATE OF TENNESSEE NOTARY PUBLIC
County of Sumner

9-27-26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Hartman

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/5/2024

Date

Board Use Only	Date Received: 4/23/24	Amount: $500 check 12.59

BEFORE THE TENNESSEE BOARD OF PHARMACY

IN THE MATTER OF:	)	
	)	
KEVIN R. HARTMAN, C-9071	)	**Case No.:**
C/O Merrill Norton	)	
Talbott Recovery Campus	)	
5448 Yorktowne Drive	)	
Altanta, Georgia 30349	)	

RECEIVED
JAN 0[illegible]
DIV. OF [illegible] BOARDS
LEGAL OFFICE

CONSENT ORDER

WHEREAS, Respondent, Kevin R. Hartman, executes this Consent Order for the purpose of avoiding further administrative action with respect to this cause;

WHEREAS, Respondent, Kevin R. Hartman is a licensee of the Tennessee Board of Pharmacy (license number: C-9071) and is therefore under its jurisdiction; and

WHEREAS, Respondent, Kevin R. Hartman acknowledges that he has become addicted to the use of alcohol, narcotics or other drugs;

WHEREAS, Respondent's acts and conduct constitutes a violation of Tenn. Code Ann. §63-10-505(3) which states in pertinent part as follows:

> The board is vested with the power and authority to place on probation, suspend, revoke or refuse to issue or renew any license or registration and, in addition, may impose a civil penalty, as defined in the rules of the board, upon a finding that the holder of such has:
> (3) Been addicted to the use of alcohol, narcotics or other drugs;
> (4) Engaged in conduct prohibited or made unlawful by any of the provisions of parts 4-6 of this chapter, or any other laws of the state or of the United States relating to drugs or to the practice of pharmacy;

WHEREAS, pursuant to Tenn. Code Ann. §63-10-505, 56-1-308, and Rule 1140-8-.01 [CIVIL PENALTIES], the Board of Pharmacy may assess a civil penalty against a person required to be licensed in the State of Tennessee to engage in the practice of pharmacy for each separate violation of the statute pertaining to the Board;

NOW THEREFORE, for the purpose of avoiding further administrative action before the Tennessee Board of Pharmacy with respect to this cause, the Respondent, Kevin R. Hartman, agrees to the following:

(1) Respondent shall surrender his license to engage in the practice of pharmacy in the State of Tennessee, license number C-9071, which shall be deemed revoked;

(2) Respondent acknowledges that he understands and agrees that this Consent Order in no way binds any other agency, division, department or political subdivision of the State of Tennessee relative to any factual allegations cited herein;

(3) The parties understand and agree that, in the event that the Tennessee Board of Pharmacy should reject this settlement, neither party is bound by any omissions, agreements, or statements made to either party during the course of discussions leading to this Consent Order;

(4) Respondent understands and acknowledges that he has the right to a hearing pursuant to Tenn. Code Ann. Uniform Administrative Procedures

Act, Title 4, Chapter 5, but he is waiving that right in order to enter into this Consent Order;

(5) Respondent expressly waives any right to seek administrative or judicial review of this Consent Order or otherwise contest its validity.

I have read and understand the above Consent Order and signed my name of my own free will without duress or coercion.

Executed this 30th day of December, 2002

KEVIN R. HARTMAN

Forrest Parmley, DPh
Chairman
Tennessee Board of Pharmacy

Kendall Lyncy, DPh
Executive Director
Tennessee Board of Pharmacy

Alison G. Zane
Staff Attorney
Tennessee Board of Pharmacy
312 8th Avenue North
25th Floor, Tennessee Tower
Nashville, Tennessee 37243-0569
(615) 741-3072

BEFORE THE TENNESSEE BOARD OF PHARMACY

IN THE MATTER OF:	)
	)
KEVIN HARTMAN	)
License #: C-9071	)
5324 Fredricksburg Way W.	)
Brentwood, Tennessee 37027	)

CONSENT ORDER FOR REINSTATEMENT

THIS MATTER comes before the Tennessee Board of Pharmacy upon Respondent's request for the reinstatement of his license to engage in the practice of pharmacy in the State of Tennessee.

Respondent, Kevin Hartman, voluntarily enters into this Consent Order and agrees to the reinstatement terms stipulated herein.

AUTHORITY AND JURISDICTION

Tenn. Code Ann. §63-10-505 states in pertinent part and Rule 1140-8-.01 of the Rules of the Tennessee Board of Pharmacy, which authorize the Board to revoke, suspend, place on probation or refuse to issue or renew any license or registration of a licensee and/or impose civil penalties on a licensee or an individual who is required to be licensed to engage in the practice of pharmacy in the State of Tennessee. The Board may impose civil penalties not to exceed one thousand dollars ($1,000.00) per violation of the applicable law and rules of the State of Tennessee and/or applicable laws of the United States relating to drugs or to the practice of pharmacy. Pursuant to Tenn. Code Ann. §63-10-504(f)(3), the Tennessee Board of Pharmacy also has the authority to reinstate a

licensee's license to engage in the practice of pharmacy in the State of Tennessee after revocation, upon a showing of good cause.

FINDING OF FACT

The Respondent's license to the engage in the practice of pharmacy in the State of Tennessee was revoked by the Respondent signing a Consent Order for the revocation of his license because he was seeking treatment for chemical dependency. At the May 14, 2003 Pharmacy Board meeting, the Respondent sought reinstatement of his Tennessee pharmacy license since he has completed chemical dependency treatment and is currently in the aftercare program with the Tennessee Pharmacists Recovery Network (TPRN).

CONCLUSION OF LAW

Tenn. Code Ann. §63-10-504(f)(3) states in pertinent part as follows: The board has the authority upon a proper showing and for good cause to reinstate any license or certificates revoked by it.

STIPULATED RESOLUTION

1. Respondent does hereby agree to the reinstatement of license number C-~~4947~~ 9071 with the following probationary conditions. Said probation shall remain in effect for a period of five (5) years, from May 14, 2003 to May 14, 2008:

(a) The Respondent shall completely abstain from the consumption of alcohol and controlled substances, except as prescribed by a duly licensed practitioner for a legitimate purpose;

(b) The Respondent shall consume no medications unless they are prescribed by his primary physician, Dr. Lee Tucker, M.D. The Respondent shall immediately notify the Board office of the name of his primary physician each time the Respondent changes primary physicians;

(c) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

(d) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);

(e) The Respondent shall be subject to perpetual, random sampling of urine, blood or bodily tissues, at his own expense, by agents of the Board;

(f) Should any sampling indicate the presence of drugs for which the Respondent does not have a valid prescription, a show cause order will be issued to determine why the probation and the Respondent's license should not be immediately revoked;

(g) The Respondent shall comply with all terms and conditions of the extended aftercare contract he entered into with Tennessee Pharmacists Recovery Network. Respondent shall return a copy of said contract with this Consent Order to the Board office;

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years; however, after a period of two (2) years, the Respondent may petition the Board for a modification of this Consent Order to remove

the restrictions upon a show of good cause. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without the permission of the Board;

(i) The Respondent shall provide written notice requesting an active license, satisfy all past due continuing education and pay all cumulative license renewal fees and any applicable penalties;

(j) The Respondent shall comply with all of the laws of the State of Tennessee and of the United States as they pertain to the practice of pharmacy;

(k) Since the Respondent's license has been inactive for less than one (1) year, the Respondent shall provide the Board with written notice requesting an active license, shall satisfy all past due continuing pharmaceutical education and shall pay all cumulative license renewal fees and any applicable penalties.

1. The presentation of this Consent Order to the Board shall not serve to disqualify any Board members from participating in a contested case hearing or probation revocation hearing should the Respondent fail to abide by the terms of this Consent Order for any reason.

2. The Board shall not seek additional punitive action as a consequence of the violations admitted in the Consent Order revoking the Respondent's license, if the Respondent complies with the terms and conditions of this Consent Order. If the Respondent breaches this Consent Order and/or fails to comply with the terms

and conditions of his probation, then the Board may hold a contested case hearing for the purpose of probation revocation and may seek remedies through the Courts.

3. The Respondent expressly waives the right to a contested case proceeding governed by the Uniform Administrative Procedures Act, Tenn. Code Ann. Title 4, Chapter 5, in order to settle this matter.

4. The Respondent expressly waives all rights to seek judicial review of this Consent Order or to otherwise contest its validity.

5. The Respondent has read and understands this Consent Order and has signed same of his own free will and without duress or coercion.

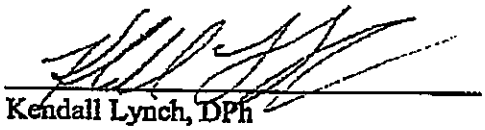
Executed this 23rd day of May, 2003.

Kevin Hartman, DPh

APPROVED:

Forrest Parmley, DPh
Chairman of the Tennessee Board of Pharmacy

Alison G. Zane, BPR #: 021965
Staff Attorney
Department of Commerce and Insurance
Office of Legal Counsel
500 James Robertson Parkway
Davy Crockett Tower, 5th Floor
Nashville, Tennessee 37243
Telephone (615) 741-3072
Facsimile (615) 741-4000



Kendall Lynch, DPh
Administrative Director
Tennessee Board of Pharmacy



I entered residential treatment for alcoholism/chemical dependency on November 20, 2002. While in treatment, I voluntarily surrendered my Tennessee pharmacist license (#9071) to the Tennessee Board of Pharmacy. Additionally, while in treatment, I signed a monitoring and advocacy contract with the Tennessee Pharmacists Recovery Network (TPRN). I successfully completed treatment on February 14, 2003. I appeared before the Tennessee Board of Pharmacy requesting license reinstatement on May 14, 2003. My Tennessee pharmacist license was successfully reinstated on May 14, 2003. Since leaving treatment, I have been active in TPRN, initially as a participant, completing my monitoring contract in May of 2008. In 2006 I also became an advocate and peer monitor with TPRN and remain active in TPRN to this day. I continue to attend regular 12 step meetings and have now been sober for over 21 years.

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

NPS PHARMACY, LLC
STE 330, BUILDING 4
278 FRANKLIN RD
BRENTWOOD, TN 37027

February 12, 2024

Request Type: Certificate of Existence/Authorization
Request #: 0568474

Issuance Date: 02/12/2024
Copies Requested: 1

Document Receipt

Receipt # : 008663639 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3867559953 — $20.00

Regarding: **NPS PHARMACY, LLC**

Filing Type:	Limited Liability Company - Domestic	Control # :	440774
Formation/Qualification Date:	01/30/2003	Date Formed:	01/30/2003
Status:	Active	Formation Locale:	TENNESSEE
Duration Term:	Perpetual	Inactive Date:	
Business County:	DAVIDSON COUNTY		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

NPS PHARMACY, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 065642524

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: NPS Pharmacy Direct	
STREET: 1417 Metroplex Dr Ste 401	
CITY: Nashville	ZIP: 37211
DATE OPENED:	TELEPHONE NO.: (615) 724-0921
LICENSE NO.: 7090	EXPIRY DATE: 2/29/2024
DEA NO.: FN0783998	EXPIRY DATE: 11/9/2024
PHARMACIST IN CHARGE/Duty: Dawn Logan Smith	LIC NO.: 38383 / EXPIRY DATE: 7/31/2024

Inspected by: Andrea Miller — Date: 2/16/2024

This Inspection Satisfactory: Yes ☑ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. - Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
✓		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours: M-F 9-5

Compliance Yes	Compliance No		
✓		19. RXs numerically filed	CYC
✓		☐ All C's together ☐ C-11's separate ☐ Multiple file method	
✓		20. Patients identifiable	
✓		21. Prescribers identifiable	
✓		22. New verbal RXs initialed by appropriate personnel	
✓		23. Date of original dispensing	
✓		24. Initials of dispensing D. Ph.	
✓		25. Quantity dispensed indicated	
N/A		26. Appropriate Emergency C-11 RXs	
✓		27. Computer labels applied appropriately to RXs	
✓		28. Pharmacist Signature Log	
N/A		29. Daily Print Out	

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling.

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS	
	N/A	36. Readily retrievable	
	N/A	37. All C-11 records separate	
	N/A	38. DEA Form 222 Copy 3 on hand & completed	
	N/A	39. Drug Receipt date on invoices	
N/A		40. Record of drug transfers	
N/A		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log	
✓		42. Last DEA Inventory (date)	5/19/2023
✓		42. Last Theft/loss report (date)	
✓		43. Access to Control Substance Monitoring Database	

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** **YES** ☐ **NO** ☒

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: No recommendations

I Dawn Logan Smith hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18

RDA SW-30

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: NPS Pharmacy Direct

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 442 Metroplex Dr, Ste 401

City: Nashville State: TN Zip: 37211

Mailing Address (if different from physical address): PO Box 157

City: Brentwood State: TN Zip: 37024

Telephone: 615-724-0924 Website: www.npspharmacy.com

Licensing Company Email: compliance@npspharmacy.com

Section 2: Personal Information

First: Kevin Middle: Last: Hartman

Alias(es, nick[redacted]changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Brentwood [redacted] Zip: 37027

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Tennessee College of Pharmacy		09/88 - 05/94	
Address	**City**	**State**	**Zip**
881 Madison Ave	Memphis	TN	38163
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
Lipscomb University		6/86 - 8/88	
Address	**City**	**State**	**Zip**
1 University Park Dr.	Nashville	TN	37204
Diploma/Degree obtained, if any			
Pre-requisite courses / NA			

School Name		From - To (MM/YY – MM/YY)	
David Lipscomb High School		8/82 - 5/86	
Address	**City**	**State**	**Zip**
3901 Granny White Pike	Nashville	TN	37204
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - 04/24	[redacted]	Brentwood	TN	37027
9/09 - 7/15	[redacted]	Nolensville	TN	37135

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or similar capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Nashville Pharmacy Services LLC			09/00 – 04/24
Business Address	**City**	**State**	**Zip**
278 Franklin Rd Ste 311	Brentwood	TN	37027
Phone	**Title**		
615-831-2291	CEO		
Description of Duties			
CEO, Pharmacist responsible for all aspects of the Pharmacy business & Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Exceed Pharmacy			07/99 – 09/00
Business Address	**City**	**State**	**Zip**
Franklin Rd	Brentwood	TN	37027
Phone	**Title**		
closed	Pharmacist		
Description of Duties			
Staff Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/8/19		TN	Franklin	Williamson
Case #:		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Williamson County Chancery Court		
Reason/Charge				
Demand of Payment				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Kevin Hartman			Lawsuit	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

McKesson Corporation filed suit against me personally as the guarantor of a business debt. McKesson ultimately agreed that my guarantee was not proper and ultimately settled with the company (Walthrite Pharmacy Services LLC) agreeing to a payment plan of re-payment

Original Signature (electronic, copies or stamps not accepted)

4/11/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/6/18	9/9/19	TN	Nashville	Davidson
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Davidson County Bankruptcy Court		
Reason/Charge				
Bankruptcy Chapter 11 Filed 12/6/18 — Bankruptcy chapter 11 reorganization plan approved & done				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Nashville Pharmacy Services LLC			Bankruptcy Chapter 11	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

Nashville Pharmacy Services LLC files for Chapter 11 bankruptcy reorganization relief 12/6/18. The bankruptcy court approved our Chapter 11 plan of reorganization on 9/9/19. All payments have either been made or remain on schedule.

Original Signature (electronic, copies or stamps not accepted)

4/4/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9/10. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/02		TN	Nashville	Davidson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		TN Board of Pharmacy		
Reason/Charge:				
Voluntarily Surrendered my personal Pharmacy license # 2071				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Kevin Hartman				
Name of Business/Industry/Entity:				
TN Board of Pharmacy				

Provide explanation below:

I voluntarily surrendered my pharmacy license in December 2002 while I sought treatment for alcoholism/chemical dependency. I successfully completed treatment on 2/14/03. In may of 2003, I agreed to have my pharmacy license reinstated. my license was reinstated in may of 2003. I remain active in 12-Step recovery. I am an advocate and peer monitor for the TN Pharmacists Recovery network. I have now been sober for 21 years and 4 months.

Original Signature (electronic, copies or stamps not accepted)

4/4/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Hartman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/4/24
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Williamson

I, Kevin Hartman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

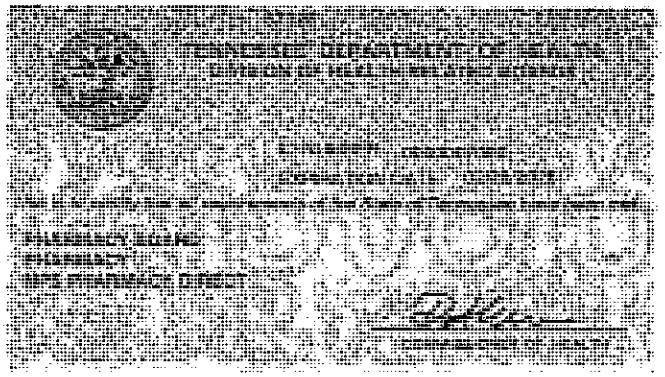
Original Signature

4/4/24
Date

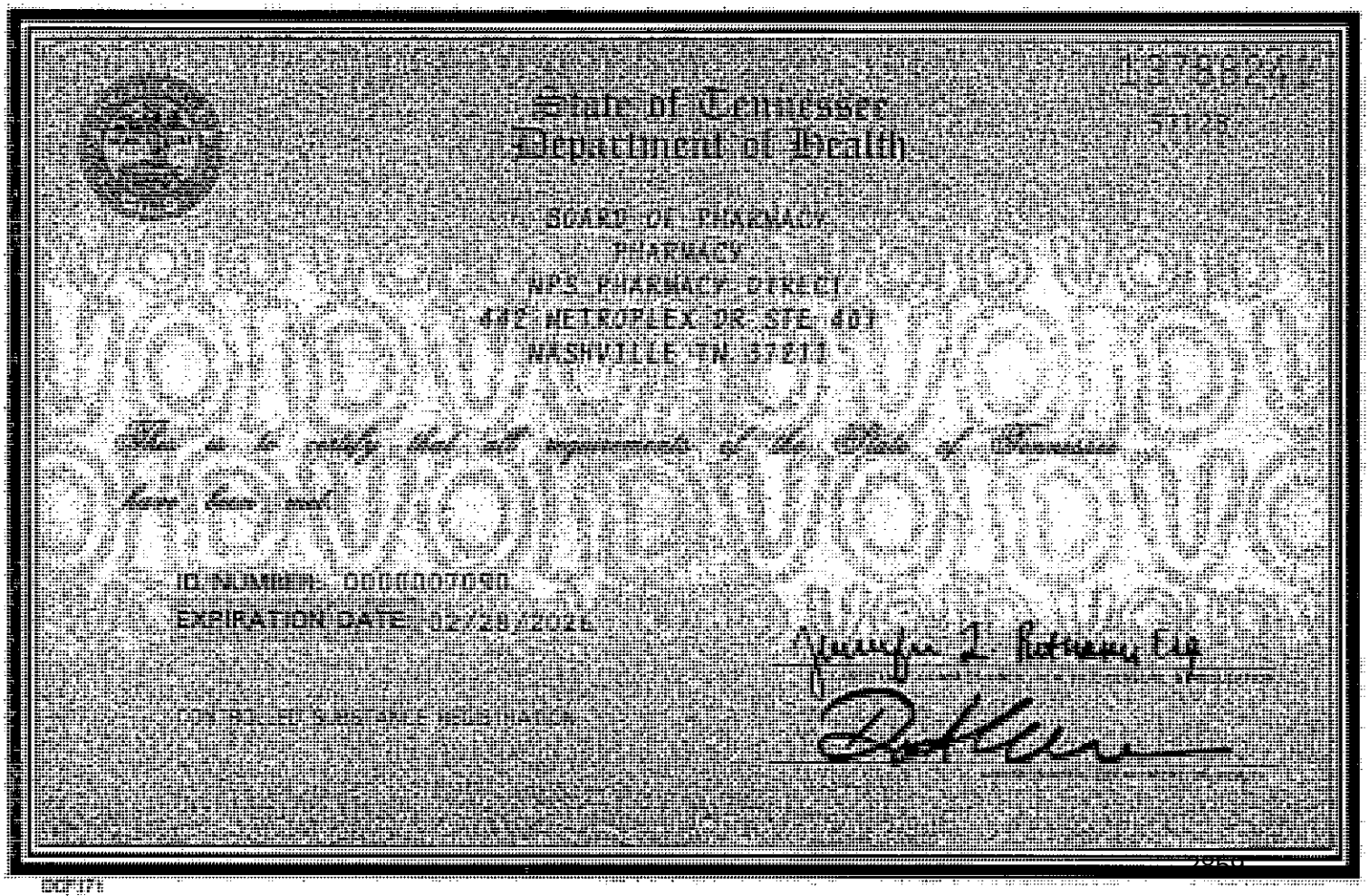
Subscribed and Sworn to before me this 4th day of April.

Notary Public Signature

KATHRYN HARTMAN
TENNESSEE
NOTARY
PUBLIC
My Comm Exp:
November 10, 2025
COUNTY OF WILLIAMSON COUNTY



NPS PHARMACY DIRECT
P.O. BOX 157
BRENTWOOD TN 37024-0157



NPS PHARMACY

NPS Officers:

Kevin Hartman, CEO & Founder

John Winnett, Chief Strategy Officer

Ashley Williams, Chief Pharmacy Officer

NPS Partners:

Kevin Hartman, CEO & Founder 100 %

Corporate Headquarters
278 Franklin Rd. Suite 330 • Brentwood, TN 37027
615-831-2291
npspharmacy.com

TN Department of Health

Health Care Facilities

Licensed Facilities

Last Updated: 9/11/2024

For more information please contact
Health Care Facilities
(615)741-7221 or 800-778-4456

Click here to return to the search page

Current Listing:
Type = Pharmacy
County = All
Results = 1

HES Pharmacy LLC
462 Morgan Dr Ste 101
Hendersonville TN 37075
615-726-0004

Permanent Shutdown Date

Facility Licensed for Controlled Substances
Status = Current
Date of Original Licensure: 08/15/2021
Date of Expiration: 07/31/2025
No Disciplinary Actions

28691

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: NPS Pharmacy Direct

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 442 Metroplex Dr, Ste 401

City: Nashville State: TN Zip: 37211

Mailing Address (if different from physical address): PO Box 157

City: Brentwood State: TN Zip: 37024

Telephone: 615-724-0924 Website: www.npspharmacy.com

Licensing Company Email: compliance@npspharmacy.com

Section 2: Personal Information

First: Aaron Middle: Logan Last: Smith

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Nashville [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ N[redacted]

Section 3: Military Service (NRS 622-120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Belmont University	1900 Belmont Blvd	Nashville	Tn	37212	08/10 – 05/14	Doctorate of Pharmacy
Murray State University	1375 Chestnut St	Murray	Ky	42071	08/04 – 05/09	—
Livingston Central High School	750 US-60	Smithland	Ky	42081	08/00 – 05/04	High School Diploma

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/22 – Present	[redacted]	Nashville	Tn	37209
09/21 – 01/22		Nashville	Tn	37206
03/19 – 09/21		Nashville	Tn	37208
03/15 – 03/19		Nashville	Tn	37207
07/11 – 03/15		Nashville	Tn	37208

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: NPS Pharmacy			From - To (MM/YY – MM/YY): 02/23 – Present
Business Address: 278 Franklin Rd Suite 330	City: Brentwood	State: Tn	Zip: 37027
Phone: 615 831 2291	Title: Pharmacist in Charge	Number of Employed Hours: 2,240	
Description of Duties: Pharmacist in Charge, dispensing, counseling, complete CMRs and track adherence			

Business Name: Optum Rx			From - To (MM/YY – MM/YY): 11/21 – 02/23
Business Address: 1021 Windcrest Court	City: Franklin	State: Tn	Zip: 37067
Phone: 615 503 1000	Title: Clinical Pharmacist	Number of Employed Hours: 2560	
Description of Duties: Completed CMR's with patients over the telephone and counseled on opportunities and gaps in care			

Business Name: Kroger Pharmacy			From - To (MM/YY – MM/YY): 07/14 – 10/21
Business Address: 2620 Elm Hill Pike	City: nashville	State: Tn	Zip: 37214
Phone: 800 576 4377	Title: Pharmacy Manager	Number of Employed Hours: 13,440	
Description of Duties: Dispensing, Counseling, completed CMRs, tracked inventory			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Aaron Logan Smith, certify that as the designated representative for NPS Direct

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ALS I am at least 21 years of age;
3. ALS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ALS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ALS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ALS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ALS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Aaron Logan Smith
Print Name (First, Last)

Aaron Logan Smith
Original Signature (electronic, copies or stamps not accepted)

4/4/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aaron Logan Smith
Print Name (First, Last)

Aaron Logan Smith
Original Signature (electronic, copies or stamps not accepted)

4/4/24
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Williamson

I, Aaron Logan Smith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Aaron Logan Smith
Original Signature

4/4/24
Date

Subscribed and Sworn to before me this 4th day of April.

Notary Public Signature

KATHRYN HARTMAN
TENNESSEE NOTARY PUBLIC
My Comm Exp. November 16, 2025
COUNTY OF WILLIAMSON COUNTY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: NPS Pharmacy Direct

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 442 Metroplex Dr, Ste 401

City: Nashville State: TN Zip: 37211

Mailing Address (if different from physical address): PO Box 157

City: Brentwood State: TN Zip: 37024

Telephone: 615-724-0924 Website: www.npspharmacy.com

Licensing Company Email: compliance@npspharmacy.com

Section 2: Personal Information

First: Kevin Middle: Last: Hartman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City: Brentwood State: TN Zip: 37027

Telephone: [redacted] Ema[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Tennessee College of Pharmacy		09/88 - 05/94	
Address	**City**	**State**	**Zip**
881 Madison Ave	Memphis	TN	38163
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
Lipscomb University		6/86 - 8/88	
Address	**City**	**State**	**Zip**
1 University Park Dr.	Nashville	TN	37204
Diploma/Degree obtained, if any			
Pre-requisite courses / NA			

School Name		From - To (MM/YY – MM/YY)	
David Lipscomb High School		8/82 - 5/86	
Address	**City**	**State**	**Zip**
3901 Granny White Pike	Nashville	TN	37204
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - 04/24	[redacted]	Brentwood	TN	37027
9/09 - 7/15	[redacted]	Nolensville	TN	37135
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Nashville Pharmacy Servizes LLC			09/00 – 04/24
Business Address	**City**	**State**	**Zip**
278 Franklin Rd Ste 311	Brentwood	TN	37027
Phone	**Title**		
615-831-2291	CEO		
Description of Duties			
CEO, Pharmacist responsible for all aspects of the Pharmacy business & Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Eckerd Pharmacy			07/99 – 09/00
Business Address	**City**	**State**	**Zip**
Franklin Rd	Brentwood	TN	37027
Phone	**Title**		
closed	Pharmacist		
Description of Duties			
Staff Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/8/19		TN	Franklin	Williamson
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Williamson County Chancery Court		
Reason/Charge				
Demand of Payment				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Kevin Hartman			Lawsuit	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

McKesson Corporation filed suit against me personally as the guarantor of a business debt. McKesson ultimately agreed that my guarantee was not proper and ultimately settled with the company (Nashville Pharmacy Services LLC) agreeing to a payment plan of re-payment

Original Signature (electronic, copies or stamps not accepted)

12/5/24
4/4/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/8/18	9/9/19	TN	Nashville	Davidson
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		Davidson County Bankruptcy Court		
Reason/Charge				
Bankruptcy Chapter 11 Filed 12/8/18 – Bankruptcy chapter 11 reorganization plan approved & done				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Nashville Pharmacy Services LLC			Bankruptcy Chapter 11	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

Nashville Pharmacy Services LLC filed for chapter 11 bankruptcy reorganization relief 12/8/18. The bankruptcy court approved our chapter 11 plan of reorganization on 9/9/19. All payments have either been made or remain on schedule.

Original Signature (electronic, copies or stamps not accepted)

12/5/24
4/4/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9/10. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/02		TN	Nashville	Davidson
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		TN Board of Pharmacy		
Reason/Charge				
Voluntarily Surrendered my personal pharmacy license # 9071				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Keith Hartman				
Name of Business/Industry/Entity				
TN Board of Pharmacy				

Provide explanation below:

I voluntarily surrendered my pharmacist license in December 2002, while I sought treatment for alcoholism/chemical dependancy. I succesfully completed treatment on 2/14/03. In may of 2003, I asked to have my pharmacist license reinstated. my license was reinstated in may of 2003. I remain active in 12-Step recovery I am an advocate and peer monitor for the TN Pharmacists Recovery Network. I have now been sober for 21 years and 4 months

12/5/24

Original Signature (electronic, copies or stamps not accepted)

4/4/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Hartman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/05/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Williamson

I, Kevin Hartman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/5/24

Date

Subscribed and Sworn to before me this 5th day of December.

Notary Public Signature

KATHRYN HARTMAN
TENNESSEE NOTARY PUBLIC
My Comm Exp. November 16, 2025
COUNTY OF WILLIAMSON COUNTY

(Seal)

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FA3984463 ☒ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Avenue Pharmacy DBA Pathway Pharmacy, Inc.

Physical Address: 202 SW 17th Street Suite A

City: Ocala State: FL Zip: 34471

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 352-624-2779 Toll Free # (NAC 639.708, NRS 639.23286): 1800-294-4512

Fax: 352-624-2779 Contact Email: Pfranck@Pathwaysrx.com

Website: www.pathwaysrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Paul Franck

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24329

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Paul Franck	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Paul Franck

Business Name: Avenue Pharmacy DBA Pathway Pharmacy, Inc.

Business Address: 202 SW 17th St Suite A

City: Ocala State: FL Zip: 34471

Telephone: 352-624-2779 Email: Pfranck@Pathwaysrx.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/Pharmacist (title) for Avenue Pharmacy DBA Pathway Pharmacy, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Franck

Print Name of Authorized Person

Paul Franck

Original signature of Authorized Person (copies or stamps not accepted)

3/26/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Franck hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner/Pharmacist (title) for Avenue Pharmacy DBA Pathway Pharmacy, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Paul Franck

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 27 day of March, 2024

Angela J Bruno

Notary Public

ANGELA J BRUNO
Notary Public - State of Florida
Commission # HH 345710
My Comm. Expires Jan 3, 2027
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Franck

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Paul Franck

Original signature of Authorized Person (copies or stamps not accepted)

3-26-24

Date

Board Use Only	Date Received: 11/15/24	Amount: $6500-cc

Department of Health

License Verification

Printer Friendly Version

PAUL WAYNE FRANCK

License Number: PS17342

Data As Of 4/4/2024

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners | Subordinate Practitioners

Emergency Actions

No Emergency Actions Found

Discipline Cases

Name	License	Profession	City	State	Case #	Action Taken
FRANCK, PAUL WAYNE	17342	PHARMACIST	OCALA	FL	199113158	OBLIGATIONS IMPOSED
FRANCK, PAUL WAYNE	17342	PHARMACIST	OCALA	FL	200817152	OBLIGATION(S) SATISFIED

Public Complaints

Name	License	Profession	City	State	Case #	Action Taken
FRANCK, PAUL WAYNE	17342	PHARMACIST	OCALA	FL	200817152	AC FILED

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance

Final Order No. DOH-12-0775-S -MQA
FILED DATE - 5-2-2012
Department of Health
By: Sandra Soto
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
Petitioner,

vs.

CASE NO.: 2008-17152
LICENSE NO.: PS 17342

PAUL WAYNE FRANCK, R.PH.,
Respondent.

_____/

FINAL ORDER APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), Florida Statutes, on April 11, 2012 in Tampa, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby ordered and adjudged:

(1) The Settlement Agreement as submitted is hereby approved, adopted and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

(2) As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are $427.17.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 18th day of May, 2012.

BOARD OF PHARMACY

Tammy Collins, Program Operations Administrator *for*
Cynthia Griffin, PharmD, Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW UNLESS WAIVED

A PARTY WHO IS ADVERSELY AFFECTED BY THIS ORDER IS ENTITLED TO JUDICIAL REVIEW, UNLESS WAIVED, PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to Paul Wayne Franck, R.Ph. at 2324 SE 15th Street, Ocala, Florida 34471; William Furlow at 2022-2 Raymond Diehl Road, Tallahassee, Florida 32308; by interoffice delivery to John Truitt, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399-3265, and by interoffice delivery to Allison Dudley, Assistant Attorney General, Department of Legal Affairs, The Capitol, PL-01, Tallahassee, Fl 32399-1050 this 2nd day of May, 2012.

Sandra Soto
Deputy Agency Clerk

7011 1570 0001 2472 6523

PS Form
Street, or PO I
City, St
Total
Restric
(Endors
For
OC

INTEROFFICE MEMORANDUM

TO: **Cassandra Pasley, BSN, JD, Chief**
Bureau of Health Care Practitioner Regulation

THRU: **Mark Whitten, Executive Director**

FROM: **Tammy Collins, Program Operations Administrator**

SUBJECT: **Delegation of Authority**

DATE: **May 1, 2012**

During Mr. Whitten's absence from the office today through close of business Monday, May 7, 2012 Tammy Collins will have delegated authority to serve as Acting Executive Director for the Board of Pharmacy/EMT/Paramedics/Rad Techs.

MW/tlc

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2008-17152**

PAUL WAYNE FRANCK, R.PH.

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy (Board) against Respondent Paul Wayne Franck, and in support alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 17342.

3. Respondent's address of record is 2324 SE 15th Street, Ocala, FL 34471.

4. At all times material to this Administrative Complaint, Respondent was the designated prescription department manager (PDM) for and employed by Franck's Lab, Inc., d/b/a Franck's Compounding Lab ("Pharmacy"), a community pharmacy located at 1240 SW 33rd Avenue, Ocala, Florida 34474.

5. At all times material hereto, the Pharmacy was not permitted by the Department of Health or otherwise authorized to engage in the wholesale distribution of prescription drugs in or into the state of Florida.

6. On or about July 15, 2008, a representative of the Department of Health ("DOH"), visited Vitreo Retinal Consultants in connection with a Medicaid audit.

7. On or about July 15, 2008, during the Medicaid audit inspection, the DOH representative discovered that the Pharmacy was selling and shipping quantities of a non-patient specific prescription drug to Vitreo Retinal Consultants.

8. Specifically, the Pharmacy sold and shipped the following quantities of Bevacizumab to Vitreo Retinal Consultants:

Date	Drug	Charges
5/6/08	#7.5 ML (150x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$2729.95
3/05/08	#15 ML (300x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$5429.95
2/07/08	#10 ML (200x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$3629.95
1/14/08	#10 ML (200x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$3629.95

9. The prescription medication sold, transferred or delivered by the Pharmacy to Vitreo Retinal Consultants as set forth in paragraph 8 above was sold, transferred or delivered to clinics and/or physicians who were not ultimate consumers or patients.

10. Section 465.018, Florida Statutes (2007), provides that no permit to operate a community pharmacy shall be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy.

11. Based on his status as PDM, Respondent is responsible for ensuring that the Pharmacy complied with the laws and rules governing the practice of pharmacy, including maintaining records and other documentation as required by the Board.

COUNT ONE

12. Petitioner realleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

13. For an indeterminate period beginning not later than on or about January 14, 2008, through a date not earlier than on or about May 6, 2008, the Pharmacy operated as a wholesale distributor by distributing prescription medication to Vitreo Retinal Consultants, who is a person other than the ultimate consumer or patient without a prescription drug wholesaler permit.

14. Section 499.003(15), Florida Statutes (2007), states: "'Distribute or distribution' means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense."

15. Section 499.012(1)(a), Florida Statutes (2007), provides that "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, with exceptions not here applicable.

16. Section 499.012(1)(b), Florida Statutes (2007), provides that "wholesale distributor" means any person engaged in the wholesale distribution of prescription drugs to a person other than a consumer or patient, with exceptions not here applicable.

17. Section 499.003(32), Florida Statutes (2007), provides that "person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any group or combination of the foregoing."

18. Section 499.01(1), Florida Statutes (2007), provides that prior to operating, a permit is required for each person and establishment that intends to operate as:

. . .

(g) A prescription drug wholesaler;

. . .

(m) A retail pharmacy drug wholesaler ... .

19. Permitting requirements for prescription drug wholesaler's permits and retail pharmacy wholesaler's permits are set forth in Section 499.012(2)(a) and (d), Florida Statutes (2007), respectively.

20. Section 499.005(22), Florida Statutes (2007), provides that failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by ss. 499.001-499.081 for that activity, is unlawful.

21. Section 465.016(1)(e), Florida Statutes (2007), provides in pertinent part that violation of Chapter 499, Florida Statutes, known as the Florida Drug and Cosmetic Act, constitutes grounds for disciplinary action by the Board of Pharmacy.

22. Based on the foregoing, Respondent is subject to discipline as prescription department manager for the Pharmacy for violating Section 465.016(1)(e), Florida Statutes (2007), by violating Sections 499.01(1), and 499.005(22) Florida Statutes, (2007), by failing to ensure that the Pharmacy obtain a prescription drug wholesaler's permit or a retail

pharmacy drug wholesaler's permit prior to engaging in wholesale distribution of prescription drugs.

COUNT TWO

23. Petitioner realleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

24. Section 499.003(37), Florida Statutes (2007), provides that "repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further distribution of the drug.

25. Section 499.003(3), Florida Statutes (2007), provides that a "repackager" is a person who repackages.

26. Section 499.01(1)(b), Florida Statutes (2007), provides that prior to operating, a permit for a prescription drug repackager is required.

27. The Respondent repackaged bevacizumab by preparing modified dosage forms of that prescription drug from the manufacturer's commercially available product which it subsequently distributed to Vitreo Retinal Consultants and to medical physician(s) associated with the clinic for subsequent dispensing to patients of the clinics, without a prescription drug repackager permit.

28. Section 499.005(22), Florida Statutes (2007), provides that it is unlawful to operate without a valid permit when a permit is required for that activity by Chapter 499, Florida Statutes.

29. Section 465.016(1)(e), Florida Statutes (2007), provides in pertinent part that violation of Chapter 499, Florida Statutes, known as the Florida Drug and Cosmetic Act, constitutes grounds for disciplinary action by the Board of Pharmacy.

30. Based on the foregoing, Respondent as PDM for the Pharmacy violated Section 465.016(1)(e), Florida Statutes, through violation of Section 499.005(22), Florida Statutes, by failure to obtain a permit prior to operation as a prescription drug repackager as required by Section 499.01(1)(b), Florida Statutes.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties on Respondent: permanent revocation or suspension of license, restriction of practice, administrative fine, reprimand, probation, corrective action, refund of fees billed or collected, remedial education, and any other relief that the Board deems appropriate.

SIGNED this 25th day of August, 2009.

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Bacton
DATE 8/26/09

Wayne L. Schiefelbein
Assistant General Counsel
Florida Bar Number 0265047
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850) 245-4640
(850) 245-4682 fax

PCP: 8.25.09

PCP Members: Powers & Jones

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses, and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a

disciplinary matter, which may include attorney hours and costs, on Respondent in addition to any other discipline imposed.

Paul Wayne Franck, R.Ph. Case No. 2008-17152

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2008-17152**

PAUL WAYNE FRANCK, R.PH.

RESPONDENTS.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaints, attached as Composite Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, PAUL WAYNE FRANCK, RPh, was a licensed pharmacist in the state of Florida, having been issued license number PS 17342. Respondent's mailing address of record is 2324 South East 15th Street, Ocala, Florida 34471.

2. Respondent was charged by Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaints, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, PAUL WAYNE FRANCK, shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **THREE THOUSAND FIVE HUNDRED DOLLARS** ($3,500.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of Law and Rules consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. **These continuing education hours shall be permitted to count toward those hours required for license renewal.** Within ten (10) days of completion of the course and/or

receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his/its mailing address and his/its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 4th day of April, 2012.

Paul Wayne Franck

PAUL WAYNE FRANCK, RPH
2008-17152

J:\PSU\Nursing\John J Truitt\Pharmacy\Stip Packs\Francks SA 2008-17152.doc

STATE OF Florida }
}
COUNTY OF Marion }

Before me personally appeared PAUL WAYNE FRANCK, RPH, whose identity is known to me or by Drivers License (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 4 day of April, 2012.

MARIETA DEEBLE
MY COMMISSION # DD940153
EXPIRES November 15, 2013
(407) 398-0153 FloridaNotaryService.com

Marieta Deeble
Notary Public
My Commission Expires:

APPROVED this 6th day of April, 2012.

STEVEN L. HARRIS, M.D., M.Sc.
Interim State Surgeon General
Florida Department of Health

NICHOLAS W. ROMANELLO
General Counsel
Florida Department of Health

WM. FREEMAN MILLER
Attorney Supervisor
Prosecution Services Unit

John J Truitt
Assistant General Counsel

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Counsel for Petitioner
John J Truitt
Florida Bar No. 0084752
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4640
Fax: 850.245.4683
Email: john_truitt@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 19823
Insp # 175052

NAME	PERMIT NUMBER	DATE OF INSPECTION
AVENUE PHARMACY INC	26742	03/21/2023
DOING BUSINESS AS		
PATHWAY PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
202 SW 17TH STREET SUITE A	352-624-2779	
CITY	**COUNTY**	**STATE/ZIP**
OCALA	MARION	FL/34471

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 AM to 6 PM
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday Y
Saturday Hours 9 AM to 1 PM	Sunday Y

Registered Pharmacist / Intern / Tech

License # PS42950	Licensee Name Devender Junuthula
License Type Registered Pharmacists	
License # RPT51072	Licensee Name Shari Defigueras
License Type Pharmacy Tech	
License # RPT41769	Licensee Name Tamara Cartagena
License Type Pharmacy Tech	
License # RPT21137	Licensee Name Margaret Ann Bartlett
License Type Pharmacy Tech	
License # RPT59357	Licensee Name Kelly M. Clark
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FA3984463	

License Relations

Pharmacy Affiliate

FRANCK, PAUL WAYNE	License # 17342

RX DPT MGR/COR/POR

FRANCK, PAUL WAYNE	License # 17342

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	Yes

Insp # 175052

INV359 - Community Requirements

AVENUE PHARMACY INC

File # 19823

Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *10/5/22 COB*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (e) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *Cardinal Health*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	Yes
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	Yes
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Insp # 175052

INV359 - Community Requirements

AVENUE PHARMACY INC

File # 19823

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

SMITH, BOBBY T

Date:3/21/2023

Representative:

William M Thomas

Date:3/21/2023

AC# 11324243

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/24/2022	PH 26742	132053

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy
Schedule II & III
3:1 Pharmacy Technician Ratio Approved

Expiration Date: **FEBRUARY 28, 2025**
AVENUE PHARMACY INC
PATHWAY PHARMACY
202 SW 17TH STREET
SUITE A
OCALA, 34471

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA3984463	06-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-24-2022

AVENUE PHARMACY INC.
DBA PATHWAY PHARMACY
202 SW 17TH ST
SUITE A
OCALA, FL 344718138

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA3984463	06-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-24-2022

AVENUE PHARMACY INC.
DBA PATHWAY PHARMACY
202 SW 17TH ST
SUITE A
OCALA, FL 344718138

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Avenue Pharmacy, Inc., dba Pathway Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH26742

Physical Address 202 SW 17th Street

City Ocala State FL Zip 34471

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 352-624-2779 Website www.pathwaysrx.com

Licensing Company Email pfranck@pathwaysrx.com

Section 2: Personal Information

First Paul Middle Wayne Last Franck

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addr[redacted]

City Ocala State FL Zip 34471

Telephone [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Coatesville High School		1971-1974	
Address	**City**	**State**	**Zip**
1445 Lincoln Hwy E	Coatesville	PA	19320
Diploma/Degree obtained, if any			
High School Degree			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		1974-1979	
Address	**City**	**State**	**Zip**
4200 Fifth Ave	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1995-present	[redacted]	Ocala	FL	34471
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Avenue Pharmacy, Inc. dba Pathway Pharmacy			2018-present	
Business Address	**City**		**State**	**Zip**
202 SW 17th St	Ocala		FL	34471
Phone	**Title**			
352-624-2779	Owner			
Description of Duties				
Pharmacist, Owner				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Wellness Infusion Centers, LLC			2022-present	
Business Address	**City**		**State**	**Zip**
202 SW 17th St Suite B	Ocala		FL	34471
Phone	**Title**			
352-353-0055	Part Owner			
Description of Duties				
Marketing				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/2008	4/2012	FL	Ocala	Marion
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2008-17152		Florida Board of Pharmacy		
Reason/Charge				
Dispensing medication to physician's office and was deemed as wholesaling				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Paul Franck/FL Board of Pharmacy				
Name of Business/Industry/Entity				
Franck's Lab, Inc.				

Provide explanation below:

We were providing eye medications to a physician's office and was looked at by the State of Florida as wholesaling. I have attached the settlement agreement.

Paul Franck

Original Signature (electronic, copies or stamps not accepted)

December 5, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Franck

Print Name (First, Last)

Paul Franck

Original Signature (electronic, copies or stamps not accepted)

December 5, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Marion

I, Paul Franck, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Paul Franck

Original Signature

12-5-2024

Date

Subscribed and Sworn to before me this 5th day of December.

Paul Franck

Notary Public Signature

MICHELLE A ALEXANDER
Notary Public, State of Florida
Commission No. HH 594678
My Comm. Exp. 09/18/28

(Seal)

Final Order No. DOH-12-0775- S -MQA
FILED DATE - 5-2-2012
Department of Health
By: Sandra Soto
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
Petitioner,

vs.

CASE NO.: 2008-17152
LICENSE NO.: PS 17342

PAUL WAYNE FRANCK, R.PH.,
Respondent.

_____/

FINAL ORDER APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), Florida Statutes, on April 11, 2012 in Tampa, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby ordered and adjudged:

(1) The Settlement Agreement as submitted is hereby approved, adopted and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

(2) As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are $427.17.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 18th day of May, 2012.

BOARD OF PHARMACY

Tammy Collins, Program Operations Administrator *for*
Cynthia Griffin, PharmD, Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW UNLESS WAIVED

A PARTY WHO IS ADVERSELY AFFECTED BY THIS ORDER IS ENTITLED TO JUDICIAL REVIEW, UNLESS WAIVED, PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to Paul Wayne Franck, R.Ph. at 2324 SE 15th Street, Ocala, Florida 34471; William Furlow at 2022-2 Raymond Diehl Road, Tallahassee, Florida 32308; by interoffice delivery to John Truitt, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399-3265, and by interoffice delivery to Allison Dudley, Assistant Attorney General, Department of Legal Affairs, The Capitol, PL-01, Tallahassee, Fl 32399-1050 this 2nd day of May, 2012.

Sandra Soto
Deputy Agency Clerk

7011 1570 0001 2472 6523

INTEROFFICE MEMORANDUM

TO: **Cassandra Pasley, BSN, JD, Chief**
Bureau of Health Care Practitioner Regulation

THRU: **Mark Whitten, Executive Director**

FROM: **Tammy Collins, Program Operations Administrator**

SUBJECT: **Delegation of Authority**

DATE: **May 1, 2012**

During Mr. Whitten's absence from the office today through close of business Monday, May 7, 2012 Tammy Collins will have delegated authority to serve as Acting Executive Director for the Board of Pharmacy/EMT/Paramedics/Rad Techs.

MW/tlc

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2008-17152**

PAUL WAYNE FRANCK, R.PH.

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy (Board) against Respondent Paul Wayne Franck, and in support alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 17342.

3. Respondent's address of record is 2324 SE 15th Street, Ocala, FL 34471.

4. At all times material to this Administrative Complaint, Respondent was the designated prescription department manager (PDM) for and employed by Franck's Lab, Inc., d/b/a Franck's Compounding Lab ("Pharmacy"), a community pharmacy located at 1240 SW 33rd Avenue, Ocala, Florida 34474.

5. At all times material hereto, the Pharmacy was not permitted by the Department of Health or otherwise authorized to engage in the wholesale distribution of prescription drugs in or into the state of Florida.

6. On or about July 15, 2008, a representative of the Department of Health ("DOH"), visited Vitreo Retinal Consultants in connection with a Medicaid audit.

7. On or about July 15, 2008, during the Medicaid audit inspection, the DOH representative discovered that the Pharmacy was selling and shipping quantities of a non-patient specific prescription drug to Vitreo Retinal Consultants.

8. Specifically, the Pharmacy sold and shipped the following quantities of Bevacizumab to Vitreo Retinal Consultants:

Date	Drug	Charges
5/6/08	#7.5 ML (150x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$2729.95
3/05/08	#15 ML (300x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$5429.95
2/07/08	#10 ML (200x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$3629.95
1/14/08	#10 ML (200x0.05ML) Bevacizumab, SDPF (0.05ML Syringe, 30G)	$3629.95

9. The prescription medication sold, transferred or delivered by the Pharmacy to Vitreo Retinal Consultants as set forth in paragraph 8 above was sold, transferred or delivered to clinics and/or physicians who were not ultimate consumers or patients.

10. Section 465.018, Florida Statutes (2007), provides that no permit to operate a community pharmacy shall be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy.

11. Based on his status as PDM, Respondent is responsible for ensuring that the Pharmacy complied with the laws and rules governing the practice of pharmacy, including maintaining records and other documentation as required by the Board.

COUNT ONE

12. Petitioner realleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

13. For an indeterminate period beginning not later than on or about January 14, 2008, through a date not earlier than on or about May 6, 2008, the Pharmacy operated as a wholesale distributor by distributing prescription medication to Vitreo Retinal Consultants, who is a person other than the ultimate consumer or patient without a prescription drug wholesaler permit.

14. Section 499.003(15), Florida Statutes (2007), states: "'Distribute or distribution' means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense."

15. Section 499.012(1)(a), Florida Statutes (2007), provides that "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, with exceptions not here applicable.

16. Section 499.012(1)(b), Florida Statutes (2007), provides that "wholesale distributor" means any person engaged in the wholesale distribution of prescription drugs to a person other than a consumer or patient, with exceptions not here applicable.

17. Section 499.003(32), Florida Statutes (2007), provides that "person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any group or combination of the foregoing."

18. Section 499.01(1), Florida Statutes (2007), provides that prior to operating, a permit is required for each person and establishment that intends to operate as:

. . .

(g) A prescription drug wholesaler;

. . .

(m) A retail pharmacy drug wholesaler ... .

19. Permitting requirements for prescription drug wholesaler's permits and retail pharmacy wholesaler's permits are set forth in Section 499.012(2)(a) and (d), Florida Statutes (2007), respectively.

20. Section 499.005(22), Florida Statutes (2007), provides that failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by ss. 499.001-499.081 for that activity, is unlawful.

21. Section 465.016(1)(e), Florida Statutes (2007), provides in pertinent part that violation of Chapter 499, Florida Statutes, known as the Florida Drug and Cosmetic Act, constitutes grounds for disciplinary action by the Board of Pharmacy.

22. Based on the foregoing, Respondent is subject to discipline as prescription department manager for the Pharmacy for violating Section 465.016(1)(e), Florida Statutes (2007), by violating Sections 499.01(1), and 499.005(22) Florida Statutes, (2007), by failing to ensure that the Pharmacy obtain a prescription drug wholesaler's permit or a retail

pharmacy drug wholesaler's permit prior to engaging in wholesale distribution of prescription drugs.

COUNT TWO

23. Petitioner realleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

24. Section 499.003(37), Florida Statutes (2007), provides that "repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further distribution of the drug.

25. Section 499.003(3), Florida Statutes (2007), provides that a "repackager" is a person who repackages.

26. Section 499.01(1)(b), Florida Statutes (2007), provides that prior to operating, a permit for a prescription drug repackager is required.

27. The Respondent repackaged bevacizumab by preparing modified dosage forms of that prescription drug from the manufacturer's commercially available product which it subsequently distributed to Vitreo Retinal Consultants and to medical physician(s) associated with the clinic for subsequent dispensing to patients of the clinics, without a prescription drug repackager permit.

28. Section 499.005(22), Florida Statutes (2007), provides that it is unlawful to operate without a valid permit when a permit is required for that activity by Chapter 499, Florida Statutes.

29. Section 465.016(1)(e), Florida Statutes (2007), provides in pertinent part that violation of Chapter 499, Florida Statutes, known as the Florida Drug and Cosmetic Act, constitutes grounds for disciplinary action by the Board of Pharmacy.

30. Based on the foregoing, Respondent as PDM for the Pharmacy violated Section 465.016(1)(e), Florida Statutes, through violation of Section 499.005(22), Florida Statutes, by failure to obtain a permit prior to operation as a prescription drug repackager as required by Section 499.01(1)(b), Florida Statutes.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties on Respondent: permanent revocation or suspension of license, restriction of practice, administrative fine, reprimand, probation, corrective action, refund of fees billed or collected, remedial education, and any other relief that the Board deems appropriate.

SIGNED this 25th **day of** August, **2009.**

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Bacton
DATE 8/26/09

Wayne L. Schiefelbein
Assistant General Counsel
Florida Bar Number 0265047
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850) 245-4640
(850) 245-4682 fax

PCP: 8.25.09

PCP Members: Powers & Jones

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses, and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a

disciplinary matter, which may include attorney hours and costs, on Respondent in addition to any other discipline imposed.

Paul Wayne Franck, R.Ph. Case No. 2008-17152

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2008-17152**

PAUL WAYNE FRANCK, R.PH.

RESPONDENTS.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaints, attached as Composite Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, PAUL WAYNE FRANCK, RPh, was a licensed pharmacist in the state of Florida, having been issued license number PS 17342. Respondent's mailing address of record is 2324 South East 15th Street, Ocala, Florida 34471.

2. Respondent was charged by Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaints, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, PAUL WAYNE FRANCK, shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **THREE THOUSAND FIVE HUNDRED DOLLARS** ($3,500.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of Law and Rules consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. **These continuing education hours shall be permitted to count toward those hours required for license renewal.** Within ten (10) days of completion of the course and/or

receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his/its mailing address and his/its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 4th day of April, 2012.

Paul Wayne Franck

PAUL WAYNE FRANCK, RPH
2008-17152

STATE OF Florida }
}
COUNTY OF Marion }

Before me personally appeared PAUL WAYNE FRANCK, RPH, whose identity is known to me or by Drivers License (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 4 day of April, 2012.

MARIETA DEEBLE
MY COMMISSION # DD940153
EXPIRES November 15, 2013
(407) 398-0153 FloridaNotaryService.com

Marieta Deeble
Notary Public
My Commission Expires:

APPROVED this 6th day of April, 2012.

STEVEN L. HARRIS, M.D., M.Sc.
Interim State Surgeon General
Florida Department of Health

NICHOLAS W. ROMANELLO
General Counsel
Florida Department of Health

WM. FREEMAN MILLER
Attorney Supervisor
Prosecution Services Unit

John J Truitt
Assistant General Counsel

J:\PSU\Nursing\John J Truitt\Pharmacy\Stip Packs\Francks SA 2008-17152.doc

Counsel for Petitioner
John J Truitt
Florida Bar No. 0084752
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4640
Fax: 850.245.4683
Email: john_truitt@doh.state.fl.us

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☒ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☒ Other: Veterinary Pharmacy	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday (ON CALL)	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DBA Santa Cruz Rx Texas Pharmacy

Physical Address: 612 FM 1885 West, Ste B

City: Weatherford State: TX Zip: 76088

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: (800)457-3801 x6890 Toll Free # (NAC 639.708, NRS 639.23286): (800)457-3801 x6890

Fax: (682)267-5715 Contact Email: tx.pharmacy@scbt.com

Website: https://www.scahealth.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Sybil Schaer, Pharm.D. (PIC)

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): #24195

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sybil Schaer, Pharm.D. (PIC)	NV Pharmacist Registration #: 24195 Temporary
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✔	

If you marked YES to any of the number questions (1-5) above, a <u>signed statement of explanation must be attached</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Santa Cruz Biotechnology, Inc.

Mailing Address: 10410 Finnell Street

City: Dallas State: TX Zip: 75220

Telephone: (800)457-3801 x3 Email: tran@scbt.com

Contact Person Name: Lani Tran (800)457-3801 x4500

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Operations Manager (title) for Santa Cruz Rx Texas Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Lani Tran

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

07/30/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sybil Schaer, Pharm.D. hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for Santa Cruz Rx Texas Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of July, 2024

Notary Public

Martin Anthony Groves
My Commission Expires
9/17/2025
Notary ID
129527564

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LANi TRAN

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

07/30/24

Date

Board Use Only	Date Received: 8/1/24	Amount: $500 ck 18759

Santa Cruz Rx Texas Pharmacy:
Owners & Officers

Incorporation Information:
Santa Cruz Biotechnology, Inc.
10410 Finnell Street Dallas, Texas 75220

TAX ID# [redacted]

State Incorporated: Delaware Date Incorporated: 7/10/1991
Resident Agent of Incorporation: John R. Stephenson
Resident Agent Address: 10410 Finnell Street Dallas, Texas 75220

Corporate Officer Information:
John Ross Stephenson
[redacted]
Weatherford, TX 76088
Title: President & CEO CoTrustee: 90%
Business: 10410 Finnell Street, Dallas, TX 75220
(214)902-3900 x3
(800)457-3801

Brenda Katharine Stephenson
[redacted]
Weatherford, TX 76088
Title: VP of Marketing & Operations Co Trustee: 10%
Business: 10410 Finnell Street, Dallas, TX 75220
(214)902-3900 x3
(800)457-3801

Lani Tuyet Tran
[redacted]
Paso Robles, CA 93446
Title: COO – Operations Manager
Business: 3600 Dry Creek Rd, Paso Robles, CA 93446
(805)237-0200 x3
(800)457-3801 x4500

Pharmacist in Charge:
Sybil Schaer, Pharm. D.
TX Lic# 47912
Issued 8/08/2009 – Expires 01/31/2026
[redacted]
Fort Worth, TX 76179
Title: Pharmacist in Charge
Business: 612 FM 1885 West, Ste B, Weatherford, TX 76088
(800)457-3801 x6890

Pharmacy Details:
DBA: Santa Cruz RX TEXAS Pharmacy
Texas Lic# 33988
Issued 9/30/2021 – Expires 9/30/2025
612 FM 1885 West, Ste B
Weatherford, TX 76088
800-457-3801 x6890

SANTA CRUZ RX TEXAS PHARMACY

612 FM 1885 W, Ste B, Weatherford, TX 76088 | (800)457-3801 x6890| tx.pharmacy@scbt.com

07/15/24

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Ste 206
Reno, NV 89521

RE: List of Stockholders/Shareholders

Dear Nevada State Board of Pharmacy:

I am writing to formally inform you that our parent corporation [Santa Cruz Biotechnology, Inc.] is a privately owned company. Although Santa Cruz Biotechnology does have the authority to issue 1,000 shares of common stock as per the certificate of corporation, no stocks have been issued. Thus, the company does not have any stockholders or shareholders.

Please let us know if you require any additional information and thank you for your attention to this matter.

Sincerely,

Santa Cruz Rx Texas Pharmacy
Sybil Schaer, Pharm.D.
Pharmacist In Charge

SANTA CRUZ RX TEXAS PHARMACY

612 FM 1885 W, Ste B, Weatherford, TX 76088 | (800)457-3801 x6890| tx.pharmacy@scbt.com

07/15/24

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Ste 206
Reno, NV 89521

RE: History of Company Statement

Dear Nevada State Board of Pharmacy:

Our affiliate company, Santa Cruz Biotechnology, Inc, made a settlement on the Consent Decree provided in the attached document. This was settled 8 years ago and they are no longer doing work regulated by the USDA. Please let us know if you require any additional information.

Sincerely,

Santa Cruz Rx Texas Pharmacy
Sybil Schaer, Pharm.D.
Pharmacist In Charge

USDA
OALJ/OHC

2016 MAY 19 PM 1:31

RECEIVED

UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE SECRETARY OF AGRICULTURE

In re:	)	AWA Docket No. 12-0536
	)	
SANTA CRUZ BIOTECHNOLOGY, INC.,	)	
	)	
Respondent.	)	
	)	
In re:	)	AWA Docket No. 15-0023
	)	
SANTA CRUZ BIOTECHNOLOGY, INC.,	)	
	)	
Respondent.	)	
	)	
In re:	)	AWA Docket No. 15-0165
	)	
SANTA CRUZ BIOTECHNOLOGY, INC.,	)	
	)	CONSENT DECISION AND
Respondent.	)	ORDER

These proceedings were instituted under the Animal Welfare Act, as amended (7 U.S.C. § 2131 et seq.)(AWA or Act), by complaints filed by the Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture, on July 19, 2012, November 4, 2014, and August 7, 2015, respectively, alleging that respondent Santa Cruz Biotechnology, Inc., willfully violated the regulations promulgated pursuant to the Act (9 C.F.R. § 1.1 et seq.)(Regulations). This decision is entered pursuant to the consent decision provisions of the Rules of Practice applicable to these proceedings (7 C.F.R. § 1.138). As used herein, the term "animal" has the meaning set forth in section 2132(g) of the Act (7 U.S.C. § 2132(g)), and in section 1.1 of the Regulations (9 C.F.R. § 1.1).

Respondent admits the jurisdictional allegations in the complaints and specifically admits that the Secretary has jurisdiction in this matter, neither admits nor denies the remaining

allegations, waives oral hearing and further procedure, and consents and agrees to the entry of this decision for the purpose of settling these proceedings. The complainant agrees to the entry of this decision.

FINDINGS OF FACT

1. Respondent Santa Cruz Biotechnology, Inc., is a Delaware corporation (No. 2267992) whose agent for service of process is United Corporate Services, Inc., 874 Walker Road, Suite C, Dover, Delaware 19904. Said respondent is registered in California (No. C1696010) and its agent for service of process is Matt Mullin, 2145 Delaware Avenue, Santa Cruz, California 95060.

2. At all times mentioned in the complaints, respondent was a research facility, as that term is defined in the Act and the Regulations, and held AWA registration number 93-R-0380.

3. At all times mentioned in the complaints, respondent was a dealer, as that term is defined in the Act and the Regulations, and held AWA license number 93-B-0192.

CONCLUSIONS OF LAW

Respondent having admitted the findings of fact set forth above, and the parties having agreed to the entry of this decision, such decision will be entered.

ORDER

1. Respondent, its agents and employees, successors and assigns, directly or through any corporate or other device, shall cease and desist from violating the Act and the Regulations and Standards.

2. Respondent is assessed a civil penalty of $3,500,000, to be paid no later than May 31, 2016, by wire transfer or by check made payable to the Treasurer of the United States.

3. AWA license number 93-B-0192 is revoked effective December 31, 2016.

4. Respondent warrants that it possesses an inventory of blood and serum obtained from its live animals on or before August 21, 2015, and has produced and could produce antibodies and other materials and products derived from such blood and serum (The 8/21/15 Inventory). Between May 20, 2016, and December 31, 2016, respondent shall not, in commerce, deliver for transportation, transport, sell, or negotiate the sale of any blood, serum, antibodies, materials, or products obtained or derived from respondent's live animals other than the blood, serum, antibodies, materials, or products in The 8/21/15 Inventory.

5. By May 31, 2016, respondent shall cease activities and operations as a "research facility," as that term is defined in the Act and the Regulations, and by written request to APHIS shall request the cancellation of research facility registration 93-R-0380.

The provisions of this order shall become effective immediately. Copies of this decision shall be served upon the parties.

SANTA CRUZ BIOTECHNOLOGY, INC.,
a Delaware corporation

By [redacted]
Mark H. Lynch
Covington & Burling LLP
One CityCenter
850 Tenth Street, N.W.
Washington, D.C. 20001-4956

Attorney for Respondent

[redacted]
Colleen A. Carroll
Samuel D. Jockel
Attorneys for Complainant

Done at Washington, D.C.,
this ____ day of May 2016

[redacted]
~~Janice K. Bullard~~
Administrative Law Judge

TEXAS STATE BOARD OF PHARMACY

July 11, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

RE: Santa Cruz Rx Texas Pharmacy (Texas Pharmacy License #33988)

Hello:

On July 2, 2024, the Texas State Board of Pharmacy (TSBP) received your request for information regarding the above-described licensee.

We have enclosed documents responsive to the request.

The Texas State Board of Pharmacy would like to request your assistance in assessing the customer service you received. We appreciate your time and input. Please use https://www.surveymonkey.com/r/WYGCJKS to access the survey.

If you need additional information, please contact Renee Slaughter, Senior Administrative Assistant, at (512) 305-8028.

Sincerely,

Open Records
Texas State Board of Pharmacy

TEXAS STATE BOARD OF PHARMACY

Re:	Santa Cruz Rx Texas Pharmacy
Address:	612 FM 1885 West, Suite B Weatherford, Texas 76088
License No.:	33988
Date Issued:	September 30, 2021
Licensure Status:	Active
Expiration Date:	September 30, 2025
Type of Pharmacy:	Community – Class A
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Santa Cruz Rx Texas Pharmacy (Texas Pharmacy License #33988) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

July 11, 2024
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

Phcy. Lic. # Per-Inspection Expiration Date: ___/___/___	**NOTICE OF INSPECTION** Texas State Board of Pharmacy 333 Guadalupe Street, Suite 3-600 Austin, Texas 78701-3942 (512) 305-8000	☑ Compliance ☐ Investigation

Name of Individual	Title	R.Ph. Lic. #	Expires
VERNON, DAVID PAUL	PIC	34901	12/31/2021

Name of Facility	Class of Pharmacy License
Santa Cruz Rx Texas Pharmacy	A

Address		
612 FM 1885 West Suite B		
City/State Weatherford , TX	Zip 76088	Phone #
DEA Registration # None	Expiration Date 	
Date 9/23/2021	Time 1:00 pm	

PURPOSE OF INSPECTION

☐ Routine	☑ Pre-Inspection	☐ Rank Change
☐ New Pharmacy	☐ Change of Ownership	☐ Reverse Rank Change
☐ Complaint	☐ Follow-up to Complaint	☐ Licensee Request
☐ Follow-up to Warning Notice	☐ Follow-up to Theft/Loss Report	☐ Sterile Compounding (High Risk)
☐ Follow-up to Disciplinary Order	☑ Other Distance Inspection	

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent Robert Moura has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the PIC for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

David P. Vernon
Signature

Witnesses: Robert Moura

Signature

Signature

7/20

Remarks

SANTA CRUZ RX TEXAS PHARMACY (INITIAL)

Due to the current Declaration of Disaster in the State of Texas, this distant Inspection was conducted remotely with David P. Vernon, PIC on 9/23/21 Facetime.

The Pharmacy met all the requirements on the pre-inspection checklist. They are good to go.

Action Taken

(1) [✓] Inspection
(2) [ ] Pre-Inspection
(3) [ ] Partial Inspection
(4) [ ] Visit
(5) [ ] Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. ~~Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement~~.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Agent of the Texas State Board of Pharmacy

David P. Vernon
Authorized Individual for the Pharmacy

9/23/21
Date

02:00 pm
Time of Completion

David P. Vernon PIC
Printed Name and Title of Authorized Individual

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

_____ I am the Pharmacist-in-Charge (PIC) of *SANTA CRUZ RX TEXAS PHARMACY*, pharmacy license number *33988*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *06/07/2022*.

_____ I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

_____ I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

_____ If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

_____ I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: _____ Date: *06/07/2022*

Printed Name: *Sybil Schaer* License No.(if applicable): *47912*

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *SANTA CRUZ RX TEXAS PHARMACY*
License Number: *33988*
Address: *612 FM 1885 WEST STE B, WEATHERFORD, TX 76088*
Phone: *(800) 457-3801 x6880*
Email:
Class of License: *A*
License Expiration: *09/30/2023*
DEA #: *None*
DEA Expiration:

Inspection Information

Type: *Compliance*
Purpose: *New Pharmacy*
Date: *06/07/2022*
Arrival Time: *11:45 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Sybil Schaer *PIC* *47912*

Witness

Robert Moura

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *SANTA CRUZ RX TEXAS PHARMACY* License Number: *33988*

Class of License: *A*

Inspection Information

Type: *Compliance* Purpose: *New Pharmacy*

Date: *06/07/2022* Arrival Time: *11:45 AM* Departure Time: *12:45 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Comment

Advised to wear identification tag or badge with name and title at all times.

Inventory Records

15. Change of PIC inventory	*Satisfactory*

Comment

Change of PIC inventory completed on: 10/18/2021

17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 11/9/2021 Zero inventory.

69. Annual controlled substance inventory *(continued)*	*Satisfactory*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Not Applicable*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Not Applicable*
05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Not Applicable*
26. Controlled substance prescription compliance	*Not Applicable*
30. Controlled substance invoices dated/initialed by pharmacist	*Not Applicable*
35. Controlled substance invoices separated	*Not Applicable*
46. Drug distribution	*Not Applicable*
53. Possession of controlled substances	*Not Applicable*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Not Applicable*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Not Applicable*
61. Supervision of supportive personnel	*Not Applicable*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
21. Data processing records complete	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Not Applicable*

Policies & Procedures

70. Required policies & procedures	*Satisfactory*
92. Automated dispensing policy & procedures	*Not Applicable*

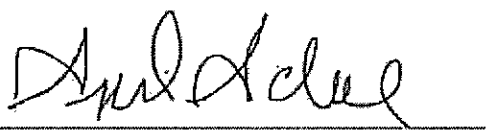
Non-Sterile Compounding

38. Area for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Sybil Schaer



Robert Moura

Texas State Board of Pharmacy

"Red Flags" Checklist for Pharmacies

YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: SANTA CRUZ RX TEXAS PHARMACY/ LIC# 33988

Address: 612 W FM1885, STE B

City: WEATHERFORD State: TX Zip: 76088

I hereby authorize the TEXAS STATE BOARD OF PHARMACY to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature] PHARM. D. (SYBIL SCHAER, PHARM.D.)

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
33988	Active	September 30, 2021	September 30, 2025

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No (see attached)	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No (see attached)
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State S
Aaron D. Briggs	Deputy General Counsel	Texas	July 11, 2024	

TEXAS BOARD OF PHARMACY

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "SANTA CRUZ BIOTECHNOLOGY, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF INCORPORATION, FILED THE TENTH DAY OF JULY, A.D. 1991, AT 9 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "SANTA CRUZ BIOTECHNOLOGY, INC.".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SANTA CRUZ BIOTECHNOLOGY, INC." WAS INCORPORATED ON THE TENTH DAY OF JULY, A.D. 1991.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





2267992 8310

SR# 20242907434

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203744459

Date: 06-18-24

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *SANTA CRUZ RX TEXAS PHARMACY*

License Number: *33988*

Address: *612 FM 1885 WEST STE B, WEATHERFORD, TX 76088*

Phone: *(800) 457-3801 x6880*

Email:

Class of License: *A*

License Expiration: *09/30/2025*

DEA #: *None*

DEA Expiration:

Inspection Information

Type: *Compliance*

Purpose: *Routine*

Date: *07/15/2024*

Arrival Time: *10:45 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Sybil Schaer *PIC* *47912*

Witness

Robert Moura

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

_____ I am the Pharmacist-in-Charge (PIC) of *SANTA CRUZ RX TEXAS PHARMACY*, pharmacy license number *33988*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *07/15/2024*.

_____ I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

_____ I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

_____ If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

_____ I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: _____ **Date:** *07/15/2024*

Printed Name: *Sybil Schaer* **License No.(if applicable):** *47912*

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *SANTA CRUZ RX TEXAS PHARMACY* **License Number:** *33988*

Class of License: *A*

Inspection Information

Type: *Compliance* **Purpose:** *Routine*

Date: *07/15/2024* **Arrival Time:** *10:45 AM* **Departure Time:** *11:45 AM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Not Applicable*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Not Applicable*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Not Applicable*

Comment

Number of balances: None

05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Not Applicable*
24. Theft/Loss	*Not Applicable*
26. Controlled substance prescription compliance	*Not Applicable*
30. Controlled substance invoices dated/initialed by pharmacist	*Not Applicable*
35. Controlled substance invoices separated	*Not Applicable*
46. Drug distribution	*Satisfactory*
53. Possession of controlled substances	*Not Applicable*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Not Applicable*
61. Supervision of supportive personnel	*Not Applicable*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*

Comment

Update complaint notification.

82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Not Applicable*

Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	*Not Applicable*
04. Balance inspection (for non-sterile compounding)	*Not Applicable*
05. Equipment Inspection	*Not Applicable*
06. Non-sterile Library	*Not Applicable*
32. Non-sterile compound label (Is label complete?)	*Not Applicable*
38. Area/Environment for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*
60. Documentation of non-sterile required training	*Not Applicable*
70. Required policies & procedures/SOPs	*Not Applicable*
87. Quality Control/Assurance	*Not Applicable*

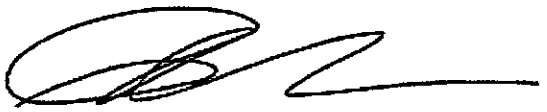
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Sybil Schaer



Robert Moura

TEXAS STATE BOARD OF PHARMACY
1801 CONGRESS AVE STE 13.100
AUSTIN TX 78701

SANTA CRUZ RX TEXAS PHARMACY
612 FM 1885 WEST STE B
WEATHERFORD TX 76088

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **33988** Expiration Date: **9/30/2025**

Balances: **0**

SANTA CRUZ RX TEXAS PHARMACY
612 FM 1885 WEST STE B
WEATHERFORD TX 76088

Julie R. Spier, R.Ph.
President

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 33988

SANTA CRUZ RX TEXAS PHARMACY

License Information

License Status Active
License # 33988
Expiration Date 09/30/2025
Date License Issued 09/30/2021

Address

612 FM 1885 WEST STE B
WEATHERFORD, TX 76088
County PARKER
Phone (800) 457-3801 x6880

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership Corporation
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
SCHAER, SYBIL

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No
Translating services (Listed Below If Available)	
Other	

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3203155 33988 SANTACRUZRXTEXASPHARMACY 2021-09 09-2026.pdf
- 3203155 33988 SANTACRUZRXTEXASPHARMACY 2022-06 06-2027.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	Yes
In-Patient Medication Orders	No

Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
POWERS, LORI LIANE	32765	08/06/1991	09/30/2025	Relief	Active
SCHAER, SYBIL	47912	08/28/2009	01/31/2026	PIC	Active

Page 1 of 1 20 View 1 - 2 of 2

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status

Page 0 of 0 20 No records to view

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
SANTA CRUZ BIOTECHNOLOGY, INC.	OWNER	10410 FINNELL STREET,	DALLAS	TX	75220
STEPHENSON, BRENDA	OFFICER	,			
TRAN, LANI TUYET	OFFICER	,			
STEPHENSON, JOHN R	OFFICER	,			

Page 1 of 1 20 View 1 - 4 of 4

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler dba SANTA CRUZ RX TEXAS PHARMACY
Pharmacy/Wholesaler License # (if applicable) (new applicant)
Physical Address 612 FM1885 WEST, STE B
City WEATHERFORD State TX Zip 76088
Mailing Address (if different from physical address) (same)
City _____ State _____ Zip _____
Telephone (800)457-3801 x6890 Website https://www.scahealth.com
Licensing Company Email tx.pharmacy@sclt.com

Section 2: Personal Information

First SYBIL Middle GUTHRIE Last SCHAER
Alias(es, nick[redacted] SYBIL GUTHRIE
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X
Mailing Address [redacted]
City FORT WORTH State TX Zip 76179
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MERCER UNIVERSITY COLLEGE OF PHARMACY		08/93 - 05/97	
Address	**City**	**State**	**Zip**
3001 MERCER UNIVERSITY DR	ATLANTA	GA	30341
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY (PHARM. D.)			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF GEORGIA		08/83 - 05/87	
Address	**City**	**State**	**Zip**
104 CALDWELL HALL	ATHENS	GA	30602
Diploma/Degree obtained, if any			
BACHELOR OF FINE ARTS			

School Name		From - To (MM/YY – MM/YY)	
MORROW HIGH SCHOOL		08/79 - 06/82	
Address	**City**	**State**	**Zip**
4930 STEELE RD	ELLENWOOD	GA	30294
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/15 - current	[redacted]	FORT WORTH	TX	76179
09/09 - 01/15	[redacted]	FORT WORTH	TX	76179

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SANTA CRUZ RX TEXAS PHARMACY			11/21 - current
Business Address	**City**	**State**	**Zip**
612 FM 1885 WEST, STE B	WEATHERFORD	TX	76088
Phone	**Title**		**Number of Employed Hours**
(800)457-3801 x6890	PHARMACIST-IN-CHARGE		5440
Description of Duties			
Manage daily pharmacy operations, dispense medications (veterinary) communication with veterinary personnel & animal owners. (next page)			

Business Name			From - To (MM/YY – MM/YY)
COMMUNITY PHARMACY			07/11 - 10/21
Business Address	**City**	**State**	**Zip**
4400 TEASLEY LN, STE 100	DENTON	TX	76210
Phone	**Title**		**Number of Employed Hours**
(940)484-4400	COMPOUNDING LAB PHARMACIST/MANAGER		21,280
Description of Duties			
Supervise sterile and non-sterile compounding lab and technician support staff. Observe processes, (next page)			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

- SANTA CRUZ (cont'd)

  Provide counseling to local and mail-order clients. Ensure adherence to Pharmacy's SOPs and procedures, maintain inventory. Maintain licensure in multiple states and adherence to state and federal regulations.

- COMMUNITY PHARMACY (cont'd)

  Develop formulas, evaluate stability and quality, research treatment modalities. Ensure <797> and <795> regulations are followed, managed ACHC certification standards, maintain staff validations and training. Interpret and dispense compounded and traditional prescriptions, communication with medical personnel, administer patient consultations and deliver immunizations

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		↘
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		↘
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		↘
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		↘
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		↘
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		↘
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		↘
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		↘
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		↘

I, SYBIL G. SCHAER, **certify that as the designated representative for**

SANTA CRUZ RX TEXAS PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SS I am at least 21 years of age;
3. SS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SYBIL G. SCHAER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/30/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SYBIL G. SCHAER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/13/24

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of TARRANT

I, SYBIL G SCHAER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/13/24

Date

Subscribed and Sworn to before me this 13TH day of JULY 2024.

Notary Public Signature

Martin Anthony Groves
My Commission Expires
9/17/2025
Notary ID
129527564

(Seal)

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application
(Only required if providing internet services)

GENERAL INFORMATION

Name of Nevada license pharmacy: (Applicant) SANTA CRUZ RX TEXAS PHARMACY

Nevada license number: pending/applying for license

Websites in use or intended to be used: https://www.scahealth.com

Affiliated websites (websites that link to or otherwise direct users to your website):

N/A

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☐ No ☑

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☑ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

JULY 2024 PHARMACY LICENSES - WEATHERFORD RX: ISSUE DATE

GEORGIA

LIC# PHNR002314 = ISSUED: 4/29/22

IDAHO

LIC# NDO75191 = ISSUED: 4/30/24

KANSAS

LIC# 22-119974 = ISSUED: 3/17/23

KENTUCKY

LIC# TX2903 = ISSUED: 6/22/22

MICHIGAN

LIC# 5301013182 = ISSUED: 3/18/24

MISSOURI

LIC# 2022007907 = ISSUED: 3/3/22

NEW YORK

LIC# 039495 = ISSUED: 3/25/22

NORTH DAKOTA

LIC#PHAR1926 = ISSUED: 3/24/22

OKLAHOMA

LIC# 99-9389 = ISSUED: 1/31/23

PENNSYLVANIA

LIC# NP001951 = ISSUED: 7/18/22

TENNESSEE

LIC# 00007652 = ISSUED: 9/15/23

TEXAS

LIC# 33988 = ISSUED: 9/30/21

WASHINGTON

LIC# PHNR.FO.61530802 = ISSUED: 4/15/24

WISCONSIN

LIC# 2883-43 = ISSUED: 7/19/22

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:

A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☑ No ☐

B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☑ No ☐

C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☑ No ☐

D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☑ No ☐

E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☑ No ☐

F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☑ No ☐

G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☑ No ☐

H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☑ No ☐

I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☑ No ☐

J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☑ No ☐

3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☑ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☒ No ☐

5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☒ No ☐

6. Does the pharmacy comply with applicable federal and state laws regarding the following:

   A) To the dispensing of prescription drugs? Yes ☒ No ☐

   B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☒ No ☐

   C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs ? Yes ☐ No ☐ N/A - Veterinary pharmacy only

7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☒ No ☐

8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia, 25th* edition, 2002, which is hereby adopted by reference? Yes ☒ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.

Signature of Owner

07/15/24
Date

TXAH0001

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
POLICY/PROCEDURE CONTROL	Effective Date November 15, 2021
Document Control Number **TXAH0001**	Revision Dates

1. PURPOSE:

To provide appropriate operational policies and procedures necessary to operate the Texas Pharmacy in accordance with Current Good Manufacturing Practices (cGMP), and other federal, state, and local governmental requirements.

2. SCOPE:

All Santa Cruz Rx Texas Pharmacy employees involved with the development, approval, and distribution of standard operating procedures.

3. RESPONSIBILITIES:

All Santa Cruz Rx Texas Pharmacy employees working within the pharmacy are expected to follow established policies and procedures. Failure to follow such procedures will result in disciplinary action according to established Personnel Policy. Exceptions/excursions from established procedures are documented and records maintained for three years.

A DOCUMENT STRUCTURE

Each policy/procedure will consist of a minimum of four elements as identified:

PURPOSE is to identify why the policy or procedure is being implemented

SCOPE identifies the individuals or the operation the document describes

RESPONSIBILITIES state the employees or functional responsibility for the procedure.

DOCUMENT CONTROL NUMBER Each policy/procedure will be numbered for easy access and referral.

B POLICY/PROCEDURE APPROVAL

All policies/procedures are released for use, only after approval by the appropriate management. The Pharmacist In Charge is responsible for reviewing and authorizing all SOPs related to the receiving, storing and shipping of products and medical devices.

C ADD/CHANGE/DELETE

Policies/procedures may be added, changed or deleted by members of management or the Pharmacist In Charge with the approval of management.

D. EFFECTIVE DATE

The policy/procedure will be placed into effect when the final approval is obtained and the document is uploaded onto the internal website. A copy of the previous edition of the procedure is retained as a reference by the Animal Health Sales Manager.

E REVIEW SCHEDULE

All policy/procedures are reviewed every two years. If revisions are not necessary, a note of "Review completed, no changes" and the "date" are entered to formalize the review. Should revisions be needed, the policy/procedure is routed through the appropriate review/authorization process, including approval by the Pharmacist In Charge.

F. REVISION HISTORY

The last page of each policy will identify a history of revisions showing the date and what was changed.

G. DISTRIBUTION OF POLICIES/PROCEDURES

The Pharmacist In Charge is responsible uploading updated SOPs to the internal website so that they can be easily retrieved by all pharmacy employees

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer PharmD	Approval:

Revision History:

Date:

TXAH0005

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
RECORDKEEPING	Effective Date November 15, 2021
Document Control Number **TXAH0005**	Revision Dates

1. PURPOSE:

The purpose of this policy is to document a standard procedure for the creation and retention of documents generated in support of the distribution of prescription products/devices during the normal course of operations at the Santa Cruz Rx Texas Pharmacy.

2. SCOPE:

This procedure is applicable to all Santa Cruz Rx Texas Pharmacy employees.

3. RESPONSIBILITIES:

The Pharmacist In Charge is responsible for ensuring that all records developed and accumulated for product and device receiving, storing and shipping are maintained according to internal procedures and those of governing regulatory agencies.

4. PROCEDURE:

Santa Cruz Rx Texas Pharmacy retains all documentation according to established regulatory guidelines for a minimum of three years, or as directed by individual manufacturer and establishes and maintains inventories and records of all transactions documenting the receipt and distribution or other disposition of all drugs and devices. These records include appropriate information and data to identify the source of the product and type of product being received or distributed.

A. DOCUMENTATION REQUIREMENTS

When corrections are needed to documentation the description of the change is noted at the end of the applicable document and the former version is maintained by the Supply Chain Manager.

B. RECORD RETENTION

1. All records supporting the receipt, inspection, processing and distribution of prescription drug products are maintained for a minimum of three years.

2. Records are kept in an organized manner so as to allow for retrieval within 48 hours of a request by an authorized agent of a government agency.

3. Upon request from an authorized official of any state, federal or government agency, drug records will be provided for inspection and photocopying.

4. If records are kept off-site, they are organized such that they can be retrieved within the 48-hour request timeframe.

5. All retained records will be stored in a secured area with restricted access. Boxed files will be marked with a date for destruction based on a minimum three-year retention period.

C. RECORD DESTRUCTION

1. Hardcopy records will be retired from the current files to secured boxed files as required by space.

2. After the three-year retention date, product files may be destroyed if no investigations are ongoing.

3. Hardcopy files containing any proprietary or customer-specific information is shredded prior to being put into the trash.

4. Hardcopy files are shredded prior to being put into the trash.

D. ELECTRONIC FILES

1. All electronic files relating to inventory and distribution are retained for at least three years from the date developed.

2. If there are no ongoing investigations, electronic files may be purged after the three-year retention date

3. All records pertaining to the transactions conducted by the wholesale distribution business is maintained within the SAP business

management software for easy retrieval by an authorized agent of a government agency.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0010

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
COMMON CARRIERS	Effective Date November 15, 2021
Document Control Number **TXAH0010**	Revision Dates

1. **PURPOSE:**

   To detail the activity involved with ensuring that common carriers used by Santa Cruz Rx Texas Pharmacy maintain appropriate security measures sufficient to meet regulatory requirements and maintain security over prescription drugs and devices throughout the delivery cycle.

2. **SCOPE:**

   This policy applies to all carriers utilized by Santa Cruz Rx Texas Pharmacy to transport prescription drug medication to the ordering end user.

3. **RESPONSIBILITIES:**

   The Pharmacist In Charge is responsible for the creation, training, implementation, review, and revision of this policy.

4. **POLICY:**

   Any Common Carrier used to distribute prescription drug products must provide a documented agreement detailing the carrier's security measures.

   AGREEMENT WITH COMMON CARRIER

   A. Any Common Carrier used to distribute prescription drug products or devices must provide a documented agreement detailing the carrier's security measures. All carriers must ensure that employees who knowingly handle or have access to prescription drugs or devices have undergone criminal background checks and drug testing.

   B. Carriers are asked to confirm details of their overall security systems.

C. Once certified as an acceptable Common Carrier, requests for re-certification will be sent by January 10th each year to potential carriers who may be called into use for the delivery of prescription drug products. This allows for backup vendors if needed.

- Certification letters from the carriers must be received in February.
- Only carriers submitting compliance letters will be considered as authorized carriers.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0020

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
FACILITY MAINTENANCE	Effective Date November 15, 2021
Document Control Number **TXAH0020**	Revision Dates

1. PURPOSE:

To provide a uniform procedure directing the activities and responsibilities involved with the maintenance of the Santa Cruz Rx Texas Pharmacy located at 612 FM 1885 West, Suite B, Weatherford, TX. 76088

2. SCOPE:

This procedure applies to the Pharmacist In Charge as they are responsible for ensuring that the pharmacy is functional, clean and organized.

3. RESPONSIBILITIES:

The Pharmacist In Charge is responsible for ensuring that appropriate employees are trained and supervised in the maintenance of the pharmacy and all areas where prescription drugs or devices may be received, stored, processed or shipped within the pharmacy area.

4. PROCEDURES:

Santa Cruz Rx Texas Pharmacy. ensures the pharmacy is clean, organized and free from pests.

A. GENERAL FACILITY MAINTENANCE

1. **Santa Cruz Rx Texas Pharmacy** is to inspect fire extinguishers and smoke alarms annually.

B. FACILITY CLEANING

Cleaning is performed by the Facilities Department under the witness of the Pharmacist in Charge.

1. Floors are kept clean and litter-free.

2. All restrooms are kept clean.

3. Detailed cleaning and maintenance schedules are maintained and monitored.

4. No product-specific labels, interior cartons, patient directives, etc. with potential for use in counterfeiting a product can be placed into trash receptacles. Should any such components need to be destroyed as scrap or unusable, they are defaced or shredded prior to placing in the trash.

5. Only approved trash can be accumulated in unsecured trash containers. This includes corrugated materials, packing material, packing tape, broken pallet wood, dirt and dust.

6. Once product specific material is shredded it is retained securely in the pharmacy until a pharmacy technician or pharmacist in charge verifies the efficacy of the destruction. The waste can be moved to a general location for final disposal once management approval is obtained.

C. PEST AND RODENT CONTROL

1. David's Pest Control is contracted to make quarterly treatments to the pharmacy. Work Order/Receipts are reviewed by management and maintained to verify that these treatments have been received.

2. The interior and exterior of the building are treated according to the contract.

3. All pest control workers are overseen by a pharmacy technician or pharmacist when performing treatments in the product/device storage and processing areas. Only exceptions are if the pest control company can provide criminal background checks or if the workers are bonded.

4. A schematic is available showing all bait traps within the pharmacy if applicable.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist in Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0025

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, Tx 75220	
INVENTORY CONTROLS	Effective Date November 15, 2021
Document Control Number **TXAH0025**	Revision Dates

1. PURPOSE:

To provide a uniform procedure detailing the Santa Cruz Rx Texas Pharmacy Inventory Control system for monitoring and controlling prescription drugs and medical device inventory.

2. SCOPE:

These procedures apply to all staff involved directly and indirectly with the receipt, storage, processing and shipping of prescription drugs and medical devices.

3. RESPONSIBILITIES:

The Pharmacist In Charge is responsible for ensuring that personnel are appropriately trained and supervised to ensure that inventory is received, tracked and shipped according to established policies and procedures.

4. POLICY:

SAP business management software tracks all prescription drugs and medical devices from receipt through distribution and maintains inventory reports for a minimum of three years.

A. INVENTORY CONTROLS

1. Inventory is controlled by both physical and electronic means. The physical environment is controlled through security of the building and staff diligence. SAP debits and credits the inventory balances as product is received and distributed.

2. Product rotation is supported by First-In, First-Out (FIFO) inventory practices unless under the direction or specific request of individual clients.

3. The intention is to purchase product only from manufacturers or their recommended suppliers. Orders are initiated and managed within SAP. Upon receipt of a shipment, packing slips, the incoming inventory and the original order in SAP are compared to ensure 100% accuracy.

4. Products are purchased from domestic sources only. Santa Cruz Rx Texas Pharmacy does not import any product for the business.

5. Should there be any package received from a source other than an established manufacturer or supplier known to have a business relationship with the pharmacy, the delivery should be refused.

B. INVENTORY RECONCILIATION

1. Physical inventory is completed every 365 days, or as needed, to maintain accurate inventory in SAP.

2. The count is performed in an orderly manner approved by the Pharmacist In Charge. The expected quantity is not known by the counter until after the count is complete

3. Reports are printed from SAP regarding the quantity and lot number expected of every item in the pharmacy. The results of the physical count are compared to this report.

4. If the physical count differs from the inventory system balance, a second and third count may be performed. If the third count results in a variance, research is performed to determine a possible cause of the variance.

5. Investigations include the review of all data relating to the product/lot number in question. The amount received is verified, along with all products pulled from the lot for order fulfillment. In-process product is tracked to ensure that all remaining in-house product by that lot number is available for verification.

6. Each order filled from the lot in question is reviewed for the possibility of incorrect quantities pulled-versus shipped.

7. If product is missing, other physical locations within the pharmacy are observed to identify whether the missing product might be located in a different area than is showing in the SAP system.

C. INVENTORY ADJUSTMENTS

1. All inventory count variances, after investigation, are corrected in SAP system as necessary to reflect the actual physical count.

2. All adjustments to inventory provide an audit trail. Only authorized individuals can make an adjustment to inventory.

3. Santa Cruz Rx Texas Pharmacy has established a Significant Loss Threshold for prescription products to be 10 units of any one product. Any loss higher than the significant loss threshold is reported to the FDA and to the Texas State Board of Pharmacy.

4. Inventory Reconciliation can be retrieved from SAP.

D. OUTDATED DRUG PRODUCTS

1. Incoming inspection procedures include the verification of expiration dating and expiration date is monitored through the SAP system.

2. Inventory reconciliation or other routine inventory reviews identify any product with expired dating is immediately physically placed in Quarantine and removed from available inventory for sale in SAP.

3. Outdated product is either returned to the manufacturer for destruction or destruction is coordinated by the Pharmacist In Charge. If the manufacturer directs the pharmacy to coordinate the destruction, itemized documentation is developed to verify the lot number, expiration date, quantity and method of destruction.

4. The above destruction documentation is provided to the manufacturer if requested. When the product is destroyed and the documentation is completed, the documentation is retained for at least three years.

E. INVESTIGATING INTERNAL LOSS OR THEFT

1. Should a loss or potential theft be identified through ongoing inventory control procedures, an investigation is initiated.

2. The Human Resources Manager is responsible for overseeing the investigation.

3. All lot numbers involved are identified and all documented distributions from those lot numbers are verified to ensure that the inventory system is accurate.

4. Security features of the pharmacy serve as tools to help investigate missing product. These include logs of ingress and egress by authorized personnel having access to the pharmacy area, as well as documentation to suggest those individuals performing such procedures as receipt, inventory, transfer, distributions or shipping of any prescription drug or medical device.

5. All investigative steps are documented, and reports are retained for a minimum of three years.

F. REPORTING SUSPICIOUS DRUG RECEIPTS/ORDERS

1. Should any incoming prescription drug or medical device raise a suspicion of possible tampering or counterfeiting, the Pharmacist In Charge will be notified, the items in question will be quarantined, and a report will be made by the Supply Chain Manager within three business days to the FDA and the Texas State Board of Pharmacy.

2. Should an order for prescription drugs or medical devices appear questionable as to quantity or customer identification, the Pharmacist In Charge shall be notified, the order placed on hold, and the supply chain manager contacted. The supply chain manager shall then file a report within three business days to the FDA and the Texas State Board of Pharmacy.

G. RETURNED GOODS

1. Undeliverable shipments are received according to established procedures and handled according to predetermined directives from the individual manufacturers. Returned prescription drugs and medical devices are automatically quarantined until disposition is determined.

2. With regard to Product Recalls a list will be maintained for comparison with incoming Returned Goods. Should a unit of Returned Goods appear on the Recall List, it will immediately be identified, placed in Quarantine, and included in the latest Recall Report.

3. Any prescription drugs or medical devices that are a part of a Returned Goods shipment or Product Recall are subject to destruction based on guidelines from the manufacturer. If the manufacturers require that said items be destroyed, destruction

documentation is prepared, including the product, lot number and quantity for destruction. Upon request, this destruction documentation is provided to the manufacturer for validation, with recall analysis, with a copy being maintained for three years.

H. IN-TRANSIT LOSSES

1. Any in-transit losses of prescription drug or medical devices will be investigated via the common carrier.

2. On-line tracking systems will be accessed to determine if the product was delivered as shipped.

3. The carrier will be notified of any in-transit losses with a request for investigation.

4. Investigation will be documented and retained for three years.

5. The Supply Chain Manager will notify FDA, and the Texas State Board of Pharmacy within three days of the completion of the investigation.

6. If carrier continues to experience in-transit losses then the carrier will not longer be considered as a viable carrier.

Animal Health Manager Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schael, PharmD	Approval:

Revision History:

Date:

TXAH0030

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
LICENSING	Effective Date November 15, 2021
Document Control Number **TXAH0030**	Revision Dates

1. PURPOSE:

This policy directs the activity involved with maintaining current federal and state licenses for the Santa Cruz Rx Texas Pharmacy.

2. SCOPE:

This procedure applies to all individuals and management responsible for the performance or oversight of licensing activities.

3. RESPONSIBILITIES:

The Pharmacist In Charge is responsible for ensuring appropriate employees receive documented training on this procedure and that required licensing is maintained.

4. POLICY:

A. LICENSING

1. All required federal and state licenses are to be current at all times. This includes but is not limited to the state of Texas Pharmacist & Pharmacy Technician licenses and all states requiring out-of-state licenses for distribution of prescription drugs and devices.

2. The Pharmacist In Charge is responsible for filing all original applications and renewals.

3. A list or log is kept of all out-of-state licenses required by the month of renewal.

4. Each month, the Pharmacist In Charge will check the list to determine which out-of-state licenses are expiring two months in the future, and will determine if renewal forms have been received.

If renewal forms are missing, the state websites will be accessed for the appropriate forms, or requests will be made of the appropriate state board of pharmacy.

5. Appropriate state license renewal forms will be completed and mailed along with the required fees. Some renewals can be accessed and completed on-line.

6. Follow-up is performed to ensure that current state licenses are received.

7. All licenses are posted in the State License Log Book and are available for review. Original licenses are in the pharmacy itself. Additionally, the Pharmacist In Charge will maintain up to date copies of all licenses.

B. STATE AND FEDERAL REGULATIONS

1. When regulatory agencies have different requirements for handling and shipping prescription drugs, Santa Cruz Rx Texas Pharmacy will comply with the more stringent law/regulation.

2. Applicable statutes/regulations are identified and implemented via the National Association of Boards of Pharmacy (NABP) and publications provided by FDA and state licensing entities.

Animal Health manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0035

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
PERSONNEL/TRAINING	Effective Date November 15, 201
Document Control Number **TXAH0035**	Revision Dates

1. **PURPOSE:**

   To provide documented details of the personnel policy in place for all employees of Santa Cruz Biotechnology, Inc. as they relate to assigned duties and responsibilities within the Santa Cruz Rx Texas Pharmacy.

2. **SCOPE:**

   This procedure applies to all employees with access to prescription drug or device receiving, storage, or shipping areas.

3. **RESPONSIBILITIES:**

   The Pharmacist In Charge is responsible for ensuring that all employees working within the pharmacy are managed and trained to appropriately carry out their responsibilities within the Santa Cruz Rx Texas Pharmacy.

4. **REFERENCED DOCUMENTS**
   Organizational Chart

5. **POLICY:**

   All Pharmacy Technicians of the Santa Cruz Rx Texas Pharmacy undergo required federal criminal background checks. They are trained in job-critical tasks, as well as regulatory agency requirements to support them in the performance of their assigned duties. Employees are expected to follow procedures and must be aware that failure to follow established procedures may result in disciplinary action, up to and including termination of employment.

A. ORGANIZATIONATIONAL CHART

1. An organizational chart is on file detailing the management reporting relationships within the Santa Cruz Rx Texas Pharmacy

2. Pharmacy specific job descriptions for each individual listed on the organization chart are available.

3. A Pharmacist of Pharmacy Technician is always present at 612 FM 1885 West, suite B while the pharmacy is open for business. This person is knowledgeable of the day-to-day activities and is involved in the review and approval of procedures impacting the receipt, storage, and distribution of drug products. Appropriate continuing education is provided to ensure this individual has the experience and training necessary to perform the required duties.

B. PERSONNEL BACKGROUND CHECKS

1. All employees with access to the pharmacy undergo a federal criminal background check. These background checks cover the past seven years. Anyone with a positive criminal background check will not be eligible to have access to the pharmacy.

2. Random criminal and drug tests may be performed on existing employees.

3. Should a random drug test or a random criminal background check on a current employee result in a positive finding, management will review the issue on an individual basis and determine the appropriate action, which may include termination of employment.

C. GENERAL PERSONNEL POLICIES

1. All employees are charged with reporting any suspicion or identification of loss/theft or diversion of product.

2. Employees are required to follow Santa Cruz Rx Texas Pharmacy procedures at all times.

3. Documentation is to be completed and maintained according to established procedures. Falsification of documents is considered a serious breach of protocol and will result in disciplinary action, up to and including termination of employment.

4. Performance evaluations may be completed on a regular basis.

D. NEW-HIRE TRAINING

1. All new hires are trained to perform their day-to-day activities.

2. Pharmacy employees must be Pharmacy Technicians or licensed Pharmacists and receive general training NABP requirements.

3. Procedures applicable to handling prescription products or medical devices are reviewed with the new hire. Specifically, procedures covering Receiving Inspection, Inventory Control, Quarantine and Shipping are required, as well as specific work directives of other aspects of their jobs.

4. On-the-job training under the observance of the Pharmacist In Charge is completed prior to an employee being assigned on-going responsibilities.

E. ON-GOING TRAINING

1. When new procedures are issued, or (relevant) revisions to current procedures occur, training is updated.

2. The Pharmacist In Charge provides the training on procedures and evaluate the knowledge/awareness of employees in carrying out the new responsibility.

F. TRAINING DOCUMENTATION

1. All training is documented

2. Rosters are maintained for any group training session, listing the attendees, the trainer and the relevant training content.

3. Hard copy training records are retained in Human Resources. Copies of training records are retained in the pharmacy area.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

TXAH0040

Santa Cruz Biotechnology, Inc. 10410 Finnell ST. Dallas, TX 75220	
PRODUCT AUTHENTICATION	Effective Date November 15, 2021
Document Control Number **TXAH0040**	Revision Dates

1. PURPOSE:

To provide a detailed procedure for use in ensuring the integrity, legitimacy and authenticity of prescription drugs and devices received into and shipped from the Santa Cruz Rx Texas Pharmacy.

2. SCOPE:

This procedure applies to all Santa Cruz Rx Texas pharmacy employees receiving, handling, storing, and processing prescription drugs and devices.

3. RESPONSIBILTIES

It is the responsibility of all employees working with incoming products/devices to be alert to the possibility of counterfeit material.

4. POLICY:

Incoming Product is inspected and verified to be authentic and received from authorized suppliers. Should any product be suspected to be counterfeit or adulterated, it is immediately quarantined until investigation is complete and appropriate reports are made to government agencies. When required, pedigrees are obtained.

A. INCOMING PRODUCT INSPECTION

1. Upon receipt, all shipments are inspected as to authenticity. This includes the comparison of the Packing Slip with both the actual product received and the products and quantities ordered within SAP, the continuity of the shipment from the specified supplier's shipping address, and the validity of the carrier. Product containers are inspected for any suspicious labeling. Comparisons are made with other products from the same manufacturer. Labels are reviewed to ensure that master cartons and interior products indicate the same product.

2. Should any product display evidence of tampering or counterfeiting, it is immediately placed in Quarantine and the Pharmacist In Charge is notified.

3. Product packaging is inspected to ensure outer and inner packaging has not been compromised and seals are intact. If anything appears suspicious then that product is removed from SAP and placed into Quarantine.

4. Incoming product is compared with current inventory of that same product. Differences are investigated to ensure all inventory is authentic prior to the incoming product is received into inventory. Any product that cannot be authenticated is immediately placed in quarantine.

5. During scheduled inventory reconciliation, products will be chosen at random in other to authenticate the material.

6. The Pharmacist In Charge validates the need for quarantine and contacts the Supply Chain Manager when appropriate.

7. The Supply Chain Manager is responsible for notifying the manufacturer or supplier of the problem as well as following up with any required investigation.

B. NOTIFICATION OF AGENCIES

1. The Supply Chain Manager is responsible for reporting any instance of suspicious products/devices to the FDA and the Texas State Board of Pharmacy within three business days.

2. All records of investigations and reporting of suspected product are maintained for a period of three years.

C. MAINTAINING SUSPICIOUS/COUNTERFEIT PRODUCT

1. Products/devices suspected as contaminated/counterfeit, are maintained in the Quarantine areas under continued temperature/humidity controls.

2. If product is to be returned to the manufacturer, documentation can be created to state adequate storage conditions were maintained throughout storage at the Santa Cruz Rx Texas Pharmacy.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0050

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
RECALLS	Effective Date November 15, 2021
Document Control Number **TXAH0050**	Revision Dates

1. **PURPOSE:**

   To define the roles and responsibilities relative to handling and reporting product recalls of any prescription product or medical device housed or shipped from the Santa Cruz Rx Texas Pharmacy

2. **SCOPE:**

   This policy applies to all product recalls directed by manufacturers or the FDA or other regulatory agency.

3. **RESPONSIBILITY:**

   All individuals involved with the receiving, storing, and shipping of prescription drugs/devices.

4. **POLICY:**

   Santa Cruz Rx Texas Pharmacy will comply with all directives from government agencies or manufacturers regarding the timely recall of any product suspected or found to have quality issues warranting a Field Alert or a Recall.

   A. RECALL CLASSIFICATION

   1. A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

   2. A Class II recall is a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

3. A Class III recall is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

NOTE: Before any recall is initiated, the FDA must be notified of a recall situation. The manufacturer, together with FDA, will decide the recall strategy and content of the recall letter.

B. RECALL STRATEGY

1. Recall Strategy is based on manufacturer directives and takes into account the following factors:

   - Results of health hazard evaluation
   - Ease in identifying the product
   - Degree to which the product's deficiency is obvious to the consumer or user
   - Degree to which the product remains in the market
   - Continued availability of essential products

2. Elements of the recall strategy will define the conduct of the recall, including:

   - Depth of recall - Consumer, Retail and/or wholesale levels
   - Public warning - General or specialized

C. EFFECTIVENESS CHECKS

Effectiveness Checks may be requested by the manufacturer and if so, will be performed to verify that all consignees at the recall depth specified have received notification of the recall and have taken action. The methods to be used for and the level of effectiveness checks conducted will be received from the client with the following classifications.

Level	Definition
A	100 % of the total consignees are contacted
B	Some percentage of the total number of consignees are contacted, as determined on a case-by-case basis, but is greater than 10% and less than 100% of consignees
C	10% of the total number of consignees are to be contacted
D	2% of the total number of consignees are to be contacted
E	No effectiveness check

D. RECALL METHODOLOGY

1. The pharmacy personnel will immediately physical place all recalled products into Quarantine and remove inventory from SAP to prevent unintentional sale.

2. If a Recall Questionnaire is received the Pharmacist In Charge will respond regardless of having the merchandise in question in stock. This will assure the manufacture the recall notice was received.

3. All manufacturer instructions will be followed.

4. The following information is available for each product shipped
   - Name and address of customer
   - Date and quantity of shipment
   - Lot number and expiration date

5. Copies of all documents will be kept on file as reference.

E. RECALL COMMUNICATIONS

The prescription drug/device manufacturer will determine how the recall will be communicated to customers.

1. The letter to the consignee must state the following.
   a. Name and strength of the product(s) being recalled.
   b. Lot number(s) of the product in question.
   c. Package fill size (100's, 120's, 1000's, etc.).
   d. Name and address of the manufacturer initiating the recall.
   e. The reason for the recall.

2. Along with the recall letter, a self-addressed, stamped post card can be sent with the questionnaire for the consignee to send back.

3. Reports will be made available to the manufacturer regarding the results of the recall activity if requested.

G. STORAGE AND HANDLING OF RECALLED PRODUCTS

Product returned due to a recall will normally go to the manufacturer. Should the manufacturer request that product be returned to Santa Cruz Rx Texas Pharmacy the following will occur to prevent the accidental misuse of returned recalled products:

1. Pharmacy personnel are alerted of the proper handling of returned product.

2. Returned recalled product is immediately placed in Quarantine status and segregated from other product.

3. The Quarantine area is isolated from the distribution locations to prevent unintended use or shipment. The accessibility to the quarantine area is limited.

4. The returned recalled products must be inventoried accurately in the quarantine area.

H. DISPOSITION OF RECALLED PRODUCT

1. Manufacturer's recall – product is collected, documented and returned to the manufacturer with a cover letter describing the reason for the return along with a full description of the product being returned.

2. Should the manufacturer request that Santa Cruz Rx, Texas Pharmacy destroy the returned recalled product, documentation for all products/devices to be destroyed will be forwarded to the manufacturer to complete the recall cycle. Copies will be maintained for three years.

3. The manufacturer is responsible for final reporting to FDA and state agencies. Santa Cruz Rx Texas Pharmacy will provide all requested information to support that reporting.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist in Charge: Sybil Schaer, PharmD	Approval:

TXAH0055

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
REPORTING THEFTS AND LOSSES	Effective Date November 15, 2021
Document Control Number **TXAH0055**	Revision Dates

1. **PURPOSE:**

To provide a uniform procedure governing Santa Cruz Rx Texas Pharmacy's method for identifying and reporting loss and theft of product in accordance with government agency requirements.

2. **SCOPE:**

This procedure applies to all employees both directly and indirectly responsible for the investigation and reporting of theft and loss of sample product.

3. **RESPONSIBILITY:**

The Human Resources Manager is responsible for investigation of loss and thefts. The Supply Chain Manager is responsible to notify the FDA and the Texas State Board of Pharmacy of these scenarios

4. **POLICY:**

Investigations will be performed to identify reasons and explanations for any loss or theft. Reports are made to the required agencies within three business days.

A. IN-TRANSIT SHIPPING LOSS OF PRODUCT

1. The freight carrier will be the first point of contact when a customer reports shipping discrepancy.

2. The Animal Health Sales Department is notified of any shipping discrepancies reported.

3. The shipment documentation is reviewed along with internal processes to ensure that the shortage did not occur in packing.

4. If discrepancies have been identified and determined to have occurred during shipping, the carrier is contacted, and a Loss Claim is initiated. Pharmacy personnel will follow up on any claims submitted to the freight company.

5. If the carrier is unable to close the claim satisfactorily, a report of in-transit loss must be sent to Supply Chain Manager for reporting to FDA and the Texas State Board of Pharmacy.

B. THEFT/LOSS OF PRODUCTS FROM THE PHARMACY

1. Should a theft or loss of product from the pharmacy be identified, an investigation will be performed according to Inventory Control procedures. The investigation may include but not be limited to:

   a. Recounting the product by lot number
   b. Reviewing past shipments for the missing product to determine if over-shipments occurred
   c. Reviewing incoming receiving reports to identify a potential miscount on receipt
   d. Review of all activity for the lot number from receipt to current date
   e. Inspection of audit trails within the inventory system to identify any adjustments relating to the product
   f. Review of any access documentation, etc.
   g. Interviewing possible witnesses or persons with knowledge.

2. All thefts are reported to FDA and the Texas State Board of Pharmacy within three days of identifying the theft.

3. All significant losses along with documentation of the investigation, are provided to the appropriate agencies.

Animal Health Manager: Jenny Chung	Approval: JC 11 4 5
Pharmacist In Charge: Sybil Schaer, PharmD	Approval: Pharm.

TKAH0060

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
SECURITY	Effective Date November 15, 2021
Document Control Number **TXAH0060**	Revision Dates

1. **PURPOSE:**

   This policy is documented to identify and explain the security system in place at the Santa Cruz Rx Texas Pharmacy located at 612 FM 1885 West; suite B, Weatherford, TX 76088.

2. **SCOPE:**

   All pharmacy employees responsible for the security of prescription products and medical devices.

3. **RESPONSIBILITIES:**

   The Pharmacist in Charge is responsible for ensuring the security system is enforced to protect prescription products and devices within the Santa Cruz Biotechnology, Texas Pharmacy. This includes the training of personnel regarding security and the oversight by Custom Security Integrated.

4. **REFERENCED DOCUMENTS:**
   Phone Tree

5. **POLICY:**

   The Santa Cruz Rx Texas Pharmacy is secured and procedures are in place to direct the monitoring and protection of products and devices to deter theft, loss or counterfeit use of devices or their components.

   A. **GENERAL SECURITY**

      1. Custom Security Integrated provides both intrusion detection and access control. The system is monitored twenty-four hours a day, seven days a week, 365 days a year.

2. If an alarm is initiated, the security company contacts the Parker Co. Sheriff's Department as well as the Central Support and Facilities Manager. A Call Tree is available to direct notification.

3. Alarms are maintained and tested on a regular schedule. Testing results are maintained for three years.

4. The composition of all trash removed from the pharmacy is monitored by a pharmacy technician or pharmacist to ensure only appropriate material is directed to the general waste stream.

5. Failure to adhere to the corporate security policies/procedures results in disciplinary action, up to and including termination of employment.

B. INTRUSION DETECTION

1. Intrusion detection is provided by motion detectors within the greater campus as well as on the doors to the pharmacy.

2. The Texas Pharmacy has access controls on all the doors to ensure that no one other than approved employees can access the prescription drug area.

3. Anyone other than a pharmacy employee with appropriate access will be under the direct supervision of a pharmacy technician or pharmacist when visiting the pharmacy area.

4. Each employee with access to the pharmacy is issued a unique entry access card and the system allows access only to specific areas based on the duties of the individual. Only employees with task critical responsibilities are allowed in the pharmacy.

5. When an employee is terminated, the entry access device is retrieved and inventoried.

C. FACILITY ACCESS

1. The outside of the building is well lit by security lighting.

2. Only those employees with responsibilities in the pharmacy (Pharmacist and pharmacy technician are allowed access. Only

the pharmacist and pharmacy technicians are allow behind the counter in the prescription fill area.

3. Only the pharmacist and pharmacy technician will have keys and security alarm codes to enter the pharmacy. Pharmacy will be locked, and alarm set of pharmacist leaves the pharmacy and the pharmacy technician is not present.
Pharmacy technician will lock the door until the pharmacist returns. No customers or other ranch staff are allowed in the pharmacy while the pharmacist is gone.

D. COMPUTER SECURITY

1. The pharmacy has a unique server with firewall protection. It is locked in the Santa Cruz Biotechnology server room and can be accessed by IT staff only.

2. Individual computers are secured through password access. Passwords are changed regularly.

3. Computers are set to time-out if no activity has occurred within 10 minutes.

E. HARD COPY SECURITY

1. All receiving, processing and distribution records are maintained for at least three years. Hard copy records are shredded or destroyed in a controlled manner upon meeting the required retention period.

2. Should any identifying labels of a product or device's immediate container, label or packaging unit need to be destroyed, they are to be defaced before being packed for destruction. This is required to prevent the use of such components in counterfeiting.

3. Only non-product specific trash is allowed in trash cans. No labels, immediate containers or other packaging components that could be used for counterfeiting device packaging will be placed in trash for normal trash removal. No actual product designated for destruction will be placed in the trash until destroyed.

4. The efficacy of the hard copy destruction is approved by a pharmacist prior to the material being removed in the pharmacy and placed into the general waste bins.

5. Documentation of hardcopy and packaging destruction is maintained in the pharmacy database on the secure pharmacy server.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist in Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0065

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
TEMPERATURE/HUMIDITY CONTROLS	Effective Date November 15, 2021
Document Control Number **TXAH0065**	Revision Dates

1. **PURPOSE:**

   To ensure that all products stored at the Santa Cruz Rx Texas Pharmacy are maintained in a controlled environment within established temperature and humidity limits. Also, it is to provide guidelines for handling any excursions from the acceptable environmental ranges.

2. **SCOPE:**

   This procedure applies to all individuals within the 612 FM 1885 West: Suite B, Weatherford, TX 76088 pharmacy involved with prescription medication handling and storage.

3. **RESPONSIBILITIES:**

   The Facilities Manager has overall responsibility for implementing this procedure, for ensuring all HVAC systems are maintained, and that any excursion outside of tolerance is addressed and documented appropriately.

4. **REFERENCED DOCUMENTS:**

   Phone Tree

5. **POLICY:**

   The pharmacy maintains an integrated HVAC system. Devices requiring refrigeration and freezing are stored under the appropriate temperatures as determined by the manufacturers.

A. TEMPERATURE AND HUMIDITY

1. The pharmacy room where products and medical devices are stored is maintained at controlled room temperature range of 68 to 77 degrees Fahrenheit. Products requiring refrigeration are stored in alarmed controlled refrigeration of 2 to 8 degrees Celsius.

2. Humidity is monitored and recorded in the pharmacy room.

3. Both temperature and humidity are monitored using sensor probes in each of the refrigerators as well as the room itself. The equipment is calibrated according to an established schedule (see below). The calibration is documented, and documentation is retained for three years.

4. Before any product is received into the pharmacy, its acceptable storage temperatures and humidity ranges will be reviewed to ensure that the environment is adequate to safely retain product integrity.

5. Products requiring specific temperature control are moved to appropriate storage within two hours of receipt.

6. The environmental system is both electronically and manually monitored with readings being documented and retained on a scheduled basis. Excursions from acceptable ranges trigger alerts to specified management team for investigation and action. The readings will be reviewed by the Central Support and Facilities Manager. Any excursions outside of the acceptable tolerances are addressed to determine root cause and corrective action.

B. TEMPERATURE/HUMIDITY MONITOR LOCATIONS

1. Environmental monitors are located.

   - In every refrigerator
   - Temperature sensor is on the ceiling, in the middle of the pharmacy.
   - Humidity sensor is on the wall by the thermostat.

C. MONITORING SCHEDULE

1. Temperature and humidity are monitored twenty-four hours a day, seven days a week by Custom Security Integrated.

2. Temperature and humidity are manually checked and recorded at least once per day by Pharmacy Technician or Pharmacist during business hours.

2. Appropriate packaging components are provided to ensure the established temperature requirements can be maintained throughout shipment. This packaging includes the use of a disposable temperature threshold indicator. Upon receiving temperature sensitive shipment, the customer will have evidence if a temperature breach occurred as well as the cumulative amount of time of the exposure.

3. Each outgoing shipment is carefully inspected for identity, lot number, expiration date, quantity as well as to the integrity of the products included in the order.

4. Product is verified against the Delivery Document to ensure that the product and quantity ordered match the product prepared for shipment, that the expiration dating and lot is adequate and that the package is appropriately packed.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

TXAH0070

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
Vendor Authentication	Effective Date November 15, 2021
Document Control Number **TXAH0070**	Revision Dates

1. **PURPOSE:**

   To provide a detailed procedure for use in assuring the legitimacy and authenticity of vendors from whom product is received into the Santa Cruz Rx Texas Pharmacy.

2. **SCOPE:**

   This procedure applies to all Santa Cruz Biotechnology, Inc. employees who establish contracts or working relationships with suppliers from which we receive product to be processed by the pharmacy.

3. **RESPONSIBILITIES:**

   The Supply Chain Manager is responsible for ensuring that all vendors providing prescription products to Santa Cruz Rx Texas Pharmacy are authenticated. This individual will notify the FDA and other federal and state agencies of any provider who cannot be authenticated.

4. **POLICY:**

   Santa Cruz Rx Texas Pharmacy receives prescription products and medical devices only from authenticated vendors.

   A. Incoming products/devices are received based on orders created in SAP. Incoming shipments are inspected for product and shipper verification to determine the actual product received matches the order.

   B. Santa Cruz Biotechnology, Inc. & Santa Cruz Rx Texas Pharmacy does not place orders or accept product from anyone other than an authenticated manufacturer or vendor. Deliveries from unknown entities are refused.

C. Suppliers are authenticated either by placing the order directly with the manufacturer, with their authorized distributor of record (ADR) or a licensed wholesaler. The identities of ADRs are obtained by calling the manufacturer or reviewing their website. Once a recommendation is received, their licenses are reviewed by the appropriate licensing state agency. Wholesalers are verified by reviewing the Texas State Board of Pharmacy website.

D. Authentication of current vendors is conducted on an annual basis by contacting both the original manufacturer to identify their ADRs as well as by contacting the appropriate licensing state agency to ensure the status is still current.

E. Records of all authentication efforts will be maintained for (3) three years.

F. If a vendor is neither authenticated nor recommended then Santa Cruz Biotechnology will not conduct business with the vendor.

G. If the vendor cannot be authenticated, the Supply Chain Manager is contacted so that notification to the FDA and the applicable state boards of pharmacy can occur within three business days.

Animal Health Manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220	
Customer Authentication	Effective Date November 15, 2021
Document Control Number **TXAH0075**	Revision Dates

1. **PURPOSE:**

   To provide a detailed procedure for use in assuring the legitimacy and authenticity of vendors from whom product is received into the Santa Cruz Rx Texas Pharmacy as well as the authentication of customers ordering prescription drug products/devices.

2. **SCOPE:**

   This procedure applies to all Santa Cruz Biotechnology, Inc. employees who process shipments of products to customers.

3. **RESPONSIBILITIES:**

   The Pharmacist In Charge is responsible for all customers ordering prescription products from Santa Cruz Rx Texas Pharmacy are authenticated. This individual works with the Supply Chain Manager to notify the FDA and other federal and state agencies of any customer ordering products/devices that cannot be authenticated.

4. **POLICY:**

   Customers are authenticated before an order is processed

Animal health manager: Jenny Chung	Approval:
Pharmacist In Charge: Sybil Schaer, PharmD	Approval:

Revision History:

Date:

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – December 2024			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SC engaged in unprofessional conduct by an APRN when she sold/dispensed dangerous drugs without having obtained a certificate of registration.	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
TH overrode a DUR alert signaling a drug-interaction with another prescription. The prescription was misfilled and provided to the incorrect patient. MW failed to provide counseling or properly counsel patient's mother.	N/A	TH and MW each fined $1,000; assessed $350 in recoverable attorney's fees and costs.	Fined $2,000; assessed $350 in recoverable attorney's fees and costs.
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employees where the patient was given clonazepam 0.5mg instead of ibuprofen and amoxicillin which resulted in patient harm.	Yes	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
MO issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country. MO participated in deceitful transactions and billed Medicaid for services that respondent did not provide.	N/A	Certificate of Registration No. CS10935 is revoked. MO cannot reapply for a period of ten years. Fined $2,500; assessed $1,754.68 in recoverable attorney's fees and costs.	N/A
PR assisted in unauthorized prescribing when she allowed her medical assistant to use her signature stamp for controlled substance prescriptions.	N/A	Fined $1,500; assessed $500 in recoverable attorney's fees and costs.	N/A
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employee who erroneously dispensed Estradoil 0.5mg and failed to counsel the patient which resulted in patient harm.	Yes	N/A	Fined $3,000.00; assessed $2,000.00 in recoverable attorney's fees and costs.

JC, as managing pharmacist, is responsible for the dispensing errors of employees that failed to dispense Doxycycline 50mg simultaneously with another prescription Metronidazole 250mg which were supposed to be taken as the prescribed course of treatment.	N/A	Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs	Fined $2,000; assessed $1,000 in recoverable attorney's fees and costs.
CD Rx failed to properly disclose that they had pending administrative actions in Alabama and Louisiana Boards of Pharmacy on their 2020 business renewal application.	N/A	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
EA failed to comply with the citation and fine dated June 30, 2023, due to his failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. EA was sent an Order to Show Cause on November 29, 2023, which he failed to appear, and a default was made. Respondent's Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A	Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A
JI failed to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. JI was sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 09672 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A

OE failed to comply with the citation and fine dated June 30, 2023, due to her failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. OE sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 16558 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	
VV is responsible for providing preprinted prescription blanks to Kindred Outpatient Wound Care Hospital. VV erroneously entered the prescriber's name Dr. L.R. on the illegal preprinted prescription blank form and dispensed several prescriptions which included a misfill of six tubes of 30g Santyl Ointment rather than one 30g tube.	N/A	Certificate of Registration No. 18969 is placed on probation for a period of two years; public reprimand; fined $5,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs.	
RR failed to make timely payments of the $500 fine and the $500 in attorney's fees and costs pursuant to the agreed upon Stipulation and Order filed September 6, 2023.	N/A	Certificate of Registration No. PT20827 is revoked and cannot petition for reinstatement for a period of one year.	N/A
KT authorized an employee to independently access, possess, store and administer dangerous drugs to patients without practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent did not establish a bona fide therapeutic relationship. In addition, Respondent falsified patient information and issued false prescriptions to obtain compounded dangerous drugs for office use.	N/A	Certificate of Registration No. CS06260 is placed on probation for a period of one year; public reprimand; fined $2,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

MS failed to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562 on October 31, 2018, where he issued 2,684 prescriptions of controlled substances to 484 patients in Nevada between November 1, 2018, and June 21, 2023, without a valid controlled substance registration and without accessing the Prescription Monitoring Program (PMP) to review the patient utilization report. Respondent MS applied for a new Certificate of Registration No. CS35699 on June 22, 2023, where he failed to comply with all the requirements for prescribing under Nevada controlled substance registration and failed to review a patient utilization report.	N/A	Certificate of Registration No. CS35699 is placed on probation for a period of two years; public reprimand; fined $16,000 for the violations; and assessed $2,500 in recoverable attorney's fees and costs.	N/A
AA prescribed electronic prescriptions for controlled substances after the Nevada Board of Pharmacy suspended his Certificate of Registration No. CS21324 due to the Nevada Board of Medical Examiners (NSBME) summarily suspending his medical license for violating his prior NSBME disciplinary orders.	N/A	Certificate of Registration No. CS21324 is revoked and cannot petition for reinstatement for a period of two years. Respondent fined $5,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
MK failed to query a PMP report for any of his prescriptions since January 19, 2016, to June 13, 2021. During the time period of January 19, 2016, to April 17, 2023, Respondent queried only two individual patients which Respondent had over 8,000 filled controlled substance prescriptions for over 6,800 patients.	N/A	Certificate of Registration No. CS23600 is fined $6,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

PO's Owner received a large shipment of drugs without the managing pharmacist's knowledge.	N/A	N/A	License No. PH04369 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $5,000 for the violations; and assessed $2,000 in recoverable attorney's fees and costs.
CS procured dangerous drugs for Aesthetics MedSpa and allowed an unlicensed person to possess, store, and/or administer these dangerous drugs without any supervision or direction by a practitioner.	N/A	Certificate of Registration No. CS27884 fined $1,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
DVH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.	N/A	N/A	License No. IB02134 fined $10,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs; quarterly inspections at the pharmacy's expense; and must maintain a perpetual inventory of all controlled substances in stock in the pharmacy.
ES is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. Respondent ES failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 19265 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A
MH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. MH failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 18203 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A

WP employees misfilled Metformin Hydrochloride ER 500mg tablets ASC, quantity 360, with two bottles of 100 tablets of Metformin Hydrochloride ER 500 MG AS tablets and one bottle of amlodipine besylate tablet, USP 5mg, quantity 500.	Yes	N/A	License No. PH02772 fined $1,000 for the violations; and assessed $750 in recoverable attorney's fees and costs.
CVS exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	N/A	License No. PH01095 fined $20,000 for the violations; assessed $750 in recoverable attorney's fees and costs; and quarterly inspections for a period of one year at the pharmacy's expense.
EN exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	Certificate of Registration No. 19578 fined $750 for the violations; and assessed $250 in recoverable attorney's fees and costs.	N/A
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00012 fined $1,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00122 fined $5,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.
NT filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called for a dose large enough to treat a 290-pound adult. Respondent recognized the error on the prescription and attempted to telephone the prescribing practitioner for clarification.	Yes	Certificate of Registration No. 23478 fined $1,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A

WP conducted business as a pharmacy without having designated and/or employed a managing pharmacist for its pharmacy location between October 6, 2023, to November 17, 2023.	N/A	N/A	License No. PH02587 fined $2,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.
NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend.	N/A	Certificate of Registration No. 20034 is revoked, and she cannot petition for reinstatement for a period of two years. Respondent fined $10,000 for the violations; and assessed $8,406.29 in recoverable attorney's fees and costs.	N/A
HM wrote 690 controlled substance prescriptions between March 18, 2018, and January 12, 2022, without having a Nevada Controlled Substance Registration.	N/A	Certificate of Registration No. PR14531 is revoked and cannot petition for reinstatement for a period of one year. Respondent fined $10,000 for the violations; and assessed $544.55 in recoverable attorney's fees and costs.	N/A
KJ prescribed 93 controlled substance prescriptions without a valid Nevada certificate of registration to prescribe controlled substances.	N/A	Certificate of Registration No. DV00607 fined $600 for the violations.	N/A
RDC is responsible for the actions of an employee who filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called for a dose large enough to treat a 290-pound adult.	Yes	N/A	License No. PH01965 fined $1000 for the violations; and assessed $500 in recoverable attorney's fees and costs.
CVS 08789 is responsible for the actions of an employee who incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	N/A	License No. PH01257 fined $1500 for the violations; and assessed $1000 in attorney's fees and costs.

OM incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	Certificate of Registration No. 23030 fined $1500 for the violations; assessed $1000 in attorney's fees and costs; and must complete ten additional continuing education courses on immunizations.	N/A
MS prescribed controlled substances and failed to maintain and actively use the prescription monitoring program (PMP) and perform queries on patients as required by Nevada Law.	No	Certificate of Registration No. CS21884 fined $5000 for the violations; assessed $1000 in attorney's fees and costs.	N/A
EW served as Medical Director for The Tox Shop where he allowed employees to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.	No	Certificate of Registration No. CS32395 is placed on probation for a period of one year; fined $2500 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
RR was the only practitioner who held a certificate of registration to dispense dangerous drugs at Family Doctors of Green Valley (FDGV). Respondent Ramanathan would engage in overseas travel on several occasions and would allow other non-licensed practitioners at FDGV to sell and/or dispense dangerous drugs and controlled substances while using his credentials.	No	Certificate of Registration No. CS14526 fined $5000 for the violations; and assessed $1500 in attorney's fees and costs.	N/A
MM subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat acute and chronic pain and subsequently surrendered his DEA Registration No. FM2307468 for cause.	No	Certificate of Registration Nos. CS18967 and PD00257 are forfeited; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A

MC stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepram, meperidine, and midazolam.	N/A	Certificate of Registration No. PT14524 is revoked, and she cannot petition for reinstatement for a period of ten years; and assessed $1500 in attorney's fees and costs as a condition of reinstatement.	N/A
GM, a non-pharmacist owner, had possession of the pharmacy keys and entered the pharmacy when no registered pharmacist was on duty, all in violation of the Board's regulation.	N/A	Certificate of Registration No. PT18868 fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
BV misfilled a prescription of escitatopram oxalate 5mg and erroneously dispensed estradiot 0.5mg. In addition, Respondent Vaknin failed to counsel the patient. Respondent Vaknin did not appear for the May 29-30, 2024, hearing and a default was taken against her registration.	Yes	Certificate of Registration No. 19231 is suspended until October 31, 2025, and must appear before the Board if she plans to renew her registration for the next biennial renewal; fined $4000 for the violations; and assessed $1988.71 in attorney's fees and costs.	N/A
WA was convicted of eight felony counts of distribution of a controlled substance.	N/A	Certificate of Registration NO. CS08254 voluntarily surrendered his Certificate of Registration No. CS08254; and assessed $1878.65 in attorney's fees and costs.	N/A
KP was involved in alcohol impairment while performing his duties as a practitioner.	N/A	Certificate of Registration No. CS10594 is revoked, and Respondent may not reapply for reinstatement for a period of two years; Respondent assessed $1614.48 in attorney's fees and costs.	N/A

HC unlawfully diverted controlled substances for his personal use.	N/A	Certificate of Registration No. PT28442 is revoked, and Respondent may not apply for reinstatement for a period of 10 years; Respondent assessed $1522.69 in attorney's fees and costs.	N/A
JS subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat pain. In addition, he failed to disclose the disciplinary action to the Nevada Board of Pharmacy on his 2016 biennial renewal application.	N/A	Certificate of Registration No. CS07913 is suspended, but the suspension is stayed and is placed on probation for a period of one year; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
ASPC provided preprinted prescription blanks and is responsible for misfilled prescriptions	N/A	N/A	License No. PH03347 is fined $5000 for the violations; and assessed $1000 in attorney's fees and costs.
KF, as managing pharmacist, is responsible recordkeeping violations related to vaccine administration.	N/A	Certificate of Registration No. 19635 is fined $500 for the violations.	N/A
EK issued prescriptions for compounded semiglutide under the names of her staff to Meta Pharmacy for administration by injection to multiple patients.	N/A	Certificate of Registration No. CS21522 is placed on probation for a period of one year; fined $2500 for the violations; assessed $1000 in attorney's fees and costs; and subject to quarterly inspections no more than $500 for a period of one year at the respondent's expense.	N/A
SB was disciplined for prescribing controlled substances without a valid registration and petitioned The Board to vacate the default Order and requested a re-hearing.	N/A	Certificate of Registration No. CS23773 request was denied.	N/A

JF at his place of practice called Century Wellness Center failed to properly label, segregate and/or dispose of adulterated and/or expired drugs, including multi-dose containers. In addition, Respondent Forsythe possessed in his inventory Veterinary 0.9% Sodium Chloride labeled “For Veterinary Use Only”.	N/A	Certificate of Registration No. CS05385 accept the Order as public reprimand regarding his duties and responsibilities as a practitioner when maintaining inventory of dangerous drugs; submit to a timely Board inspection at his practice; fined $5000 for the violations; and assessed $2384.08 in attorney’s fees and costs.	N/A
KB failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 22 separate controlled substance prescriptions. In addition, Respondent Burgner failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from December 10, 2015, to June 23, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS15148 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A
RG failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 2 separate controlled substance prescriptions. In addition, Respondent Gonzalez failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from January 29, 2018, to April 7, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS11387 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A
CVS is responsible for the acts of its employees who made an error in prescription that resulted in a negative outcome to the patient.	Yes	N/A	License No. PH02471 fined $2,000 for the violations; and assessed $1,000 in attorney’s fees and costs.

AJ is responsible for an error in a prescription that resulted in a negative outcome to the patient.	Yes	Certificate of Registration No. 23280 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
NA, as verifying pharmacist, Respondent Aguas failed to review the actual physical contents of the prescription and is responsible for an error in the prescription.	Yes	Certificate of Registration No. 14977 fined $500 for the violations.	N/A
CVS, as pharmacy owner, CVS Pharmacy #8806 is responsible for the acts of its employees who made an error in prescription.	Yes	N/A	License No. PH100640 fined $5,000 for the violations; and assessed $4,787.82 in attorney's fees and costs.
MV did not conduct a MyRx review for all prescriptions Respondent has written for part of the calendar years 2017, 2019, and 2021. Respondent only queried nine times between January 1, 2018, to September 18, 2023, where he wrote at least 890 prescriptions for at least 650 unique patients	No	Certificate of Registration No. CS15506 shall accept this as a public reprimand; must comply with all PMP related laws and regulations; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
CVS is responsible for the acts of an employee-pharmacist who failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	N/A	License No. PH01336 is fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
DM failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	Certificate of Registration No. 14845 is fined $1,000 for the violations; assessed $500 in attorney's fees and costs; and shall complete four additional continuing education credits on the topic of counseling.	N/A

NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend and was disciplined by the Board at the April 17-18, 2024, Board Meeting. Thereafter, NS petitioned the Board for reconsideration of the discipline imposed and appeared at the July 17, 2024, Board Meeting. The Board amended the discipline imposed against NS.	No	Certificate of Registration No. 20034 is revoked; however, the revocation is stayed and Respondent is placed on probation for a period of five years; fined $5,000 for the violations; assessed $8,406.29 in attorney's fees and costs; as a condition of probation, Respondent's authority to engage in the practice of pharmacy is suspended for a period of one year from April 18, 2024; and Respondent must complete a 22-hour "Ethics and Professionalism" bootcamp course within 120 days of the Order.	N/A
WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01938 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01964 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
GO made an error in a prescription that resulted in a negative outcome to a patient	Yes	Certificate of Registration No. 15190 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01064 fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.

YJ engaged in unprofessional conduct when she made an error in a prescription that resulted in a negative outcome to a patient.	Yes	Certificate of Registration No. 18030 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, AP is responsible for the acts of employees that caused a patient with acute bipolar disorder to go without medication for more than thirty days.	Yes	N/A	License No. PH03988 fined $3,000 for the violations; and assessed $2,000 in attorney's fees and costs.
DL allowed his medical assistant to use his credentials to issue electronic prescriptions for controlled substances.	No	Certificate of Registration No. CS06509 fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
Respondent Palumbo permitted registered nurses (RNs) to independently access, possess and administer dangerous drugs, without direct practitioner supervision.	No	Certificate of Registration No. CS26034 is placed on probation for a period of one year; fined $2,500 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
As managing pharmacist at the time of the events herein, TS is responsible for the acts of its employees at AWP who compounded and sold drug products using active ingredients that 1) do not have a United States Pharmacopoeia-National Formulary monograph; 2) are not a part of an FDA approved drug product, or 3) are not authorized to be used in compounding. In addition, the pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.	No	Certificate of Registration No. 08312 is placed on probation for a period of one year; fined $2,000 for the violations; assessed $1,000 in attorney's fees and costs; shall not work as a managing pharmacist of any compounding pharmacy licensed by the Board while on probation; shall not engage in the practice of compounding sterile drug products until he completes 20 extra hours of continuing education (CE) on sterile compounding; and shall complete 10 extra hours of continuing education (CE) on nonsterile compounding.	N/A

AWP is responsible for the acts of its employees who compounded and sold drug products using active ingredients that 1) do not have a United States Pharmacopoeia-National Formulary monograph; 2) are not a part of an FDA approved drug product, or 3) are not authorized to be used in compounding. In addition, the pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.	No	N/A	License No. PH02705 is suspended a period of one year, and the suspension is stayed. Respondent fined $8,000 for the violations; assessed $2,000 in attorney's fees and costs; shall not compound sterile drug products during probation period; shall bear and reimburse the Board for quarterly inspection costs in an amount not to exceed $500 per quarterly inspections; shall put into practice all necessary policies and procedures for compounding and dispensing drug products in conformance with federal and state law.
As pharmacy/pharmacy owner, SP is responsible for the acts of its employees who discarded approximately 58,000 prescription records constituting Protected Health Information (PHI) in a in violation of SP company policies and federal/state law.	No	N/A	Pharmacy License No. PH00758 fined $5,000 for the violations; and assessed $2,500 in attorney's fees and costs.
As managing pharmacist at the time of the events herein, LS is responsible for the acts of employees of SP who discarded approximately 58,000 prescription records constituting Protected Health Information (PHI) in violation of SP company policies and federal/state law.	No	Certificate of Registration No. 12687 is suspended until October 31, 2025, and must appear before the Board if she wants to renew/reinstate registration.	N/A
As pharmacy/pharmacy owner, CS is responsible for the acts of its employees who failed to keep a readily accessible paper copy of the prescription for a period of at least two years.	No	N/A	License No. PH01422 fined $500 for the violations; and assessed $500 in attorney's fees and costs.

FE pre-signed two controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel outside of the United States.	No	Certificate of Registration No. CS23430 is revoked; the revocation is stayed, and Respondent is placed on probation for a period of three years; assessed $4,268.97 in attorney's fees and costs; shall complete two hours of training from Board staff on the Nevada Prescriptions Monitoring Program (PMP) compliance; shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs.	N/A
As pharmacy/pharmacy owner, CS is responsible for the acts of its employees who initially dispensed 14 of 56 prescribed tablets of Oxycodone 10 mg to patient T.E., and later dispensed 56 additional tablets on the same prescription, thereby exceeding the prescribed quantity by 14 tablets; pharmacy employees also failed to counsel the patient.	No	N/A	License No. PH01932 fined $1,500 for the violations; and assessed $500 in attorney's fees and costs.
NS is responsible for the acts of the employees whom she supervised; the employees in question initially dispensed 14 of 56 prescribed tablets of Oxycodone 10 mg to patient T.E., and later dispensed 56 additional tablets on the same prescription, thereby exceeding the prescribed quantity by 14 tablets; Respondent also failed to counsel the patient.	No	Certificate of Registration No. 18099 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

CD failed to disclose that she previously surrendered her certificate of registration to prescribe controlled substances as issued by the federal Drug Enforcement Administration (DEA). In addition, she admits that she responded “no” to questions on the Board’s application asking whether she had “been the subject of a board citation or administrative action whether completed or pending in any state.”	No	Certificate of Registration Nos. CS35349 and DV00822 are revoked for a period of one year or until she can secure a DEA registration number in Nevada, whichever is later; fined $1,000 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
TB failed to access the Prescription Monitoring Program (PMP) database for the purpose of reviewing her prescribing activity and did not review patient utilization reports in instances where such review was required between 2016 and 2023.	No	Certificate of Registration No. CS12793 fined $2,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
AB failed to access the Prescription Monitoring Program (PMP) database for the purpose of prescribing activity and did not review patient utilization reports in instances where such review was required between December 16, 2019, to July 31, 2023.	No	Certificate of Registration No. CS29531 fined $2,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
NK never conducted “MyRx” reviews of all the prescriptions that he has written and only conducted three queries on individuals between January 1, 2018, and August 8, 2023. During the time, Respondent wrote over 500 prescriptions for at least 70 unique patients. In addition, Respondent never acquired the means of prescribing prescriptions for controlled substances electronically, despite writing at least forty-five prescriptions for controlled substances to at least 13 unique patients after January 1, 2022, when the Board ceased giving out waivers for the electronic prescription requirement.	No	Certificate of Registration No. CS09587 fined $7,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A

HZ wrote a prescription of buprenorphine, a Schedule III controlled substance, when she did not hold an active DEA registration number because she inadvertently allowed her registration to expire without renewal on May 31, 2021.	No	Certificate of Registration Nos. CS09628 and DV00543 fined $5,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
WP is responsible for the acts of its employees who failed to communicate matters which would enhance therapy through drugs to patient concerning his prescription for codeine-guaifenesin.	No	N/A	Pharmacy License No. PH01628 fined $750 for the violations; and assessed $500 in attorney's fees and costs.
SS failed to communicate matters which would enhance therapy through drugs to patient concerning his prescription for codeine-guaifenesin.	No	Certificate of Registration No. 20772 fined $750 for the violations; and assessed $500 in attorney's fees and costs.	N/A
AM failed to disclose on her October 21, 2022, controlled substance renewal application that her nursing license was on probation. In addition, Respondent did not properly answer the questions on her controlled substance registration renewal posing the following questions: 1) "Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state?; and 2) "Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state?"	No	Certificate of Registration No. CS30357 is revoked for a period of one year; and assessed $687.67.	N/A
JS diverted several tablets of butalbital-aspirin-caffeine-codeine for personal use to ease her migraine headaches.	No	Certificate of Registration No. PT24955 is revoked for a period of one year; and assessed $534.36 in attorney's fees and costs.	N/A

PCOE committed unprofessional conduct when they failed to employ a Board approved MDEG Administrator and timely submit a change of ownership.	No	N/A	License No. MP00109 fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
MD issued a controlled substance prescription after the suspension of his Certificate of Registration No. CS26423, issued thirty-seven controlled substances prescription in Nevada utilizing his DEA registration for Tennessee, failed to disclose criminal charges on his biennial renewal application, and failed to disclose the suspension of his license to practice osteopathic medicine.	No	Certificate of Registration No. CS26423 is revoked; the revocation is stayed and Respondent is placed on probation for a period of three years subject to the following conditions: 1) the Stipulation and Order is a public reprimand; 2) Respondent fined $7,000 for the violations; and 3) Respondent assessed $3,000 for attorney's fees and costs.	N/A
LPWC dispensed adulterated/and or misbranded sterile drug products that were not compounded in compliance with Nevada Law, administered compounded drug products to patients in violation of Nevada Law, and failed to maintain records accounting for all dangerous drugs.	No	N/A	Pharmacy License No. PH04520 is revoked; the revocation is stayed and Respondent is placed on probation for a period of three years subject to the following conditions: 1) Respondent fined $12,000 for the violations; 2) Respondent assessed $2,000 for attorney's fees and costs; 3) Prior to compounding sterile drug products, Laughlin Pharmacy shall comply with certain training and inspection requirements.
DP dispensed adulterated/and or misbranded sterile drug products into Nevada that were not compounded in compliance with Nevada Law, and without the authority to dispense compounded drug products.	No	N/A	Pharmacy license No. PH04171 is revoked; Respondent may not apply petition for reinstatement for a period of ten years; fined $20,000 for the violations; and assessed $2,000 in attorney's fees and costs.

YS dispensed adulterated/and or misbranded sterile drug products that were not compounded in compliance with Nevada Law, administered compounded drug products to patients in violation of Nevada Law, and failed to maintain records accounting for all dangerous drugs.	No	Certificate of Registration No. 18704 is revoked; the revocation is stayed and Respondent is placed on probation for a period of five years subject to the following conditions: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $2,000 for attorney's fees and costs; 3) Beginning sixty days after the effective date of this Order, Respondent Seo shall not work as a managing pharmacist of any pharmacy licensed by the Board for the remainder of probation; 4) Respondent Seo shall not engage in the practice of compounding sterile drug products for one year from the effective date of the Order, and shall complete certain training on compounding sterile and nonsterile drug products.	N/A
WS made misleading statements or material omissions to various professional licensing boards regarding applications for licensure in jurisdictions other than Nevada, thus subjecting himself to reciprocal discipline in Nevada.	No	Certificate of Registration No. CS27754 accepts this Stipulation and Order as a public reprimand; and assessed $750 in attorney's fees and costs.	N/A

TV dispensed adulterated/and or misbranded sterile drug products that were not compounded in compliance with Nevada Law, administered compounded drug products to patients in violation of Nevada Law, and failed to maintain accounting for all dangerous drugs.	No	Certificate of Registration No. 18661 is revoked; the revocation is stayed and Respondent is placed on probation for a period of five years subject to the following conditions: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $2,000 for attorney's fees and costs; 3) Respondent Vo shall not work as a managing pharmacist of any pharmacy licensed by the Board; 4) Respondent Vo shall not hold an ownership interest in any pharmacy licensed by the Board; 5) Respondent Vo shall not engage in the practice of compounding sterile drug products for one year from the effective date of the Order, and shall complete certain training on compounding sterile and nonsterile drug products.	N/A
JT engaged in unprofessional and deceitful conduct when he failed to properly safeguard, and promptly report the loss of, controlled substances used by him in his veterinary practice. The respondent was aware of the December 4, 2024, Board hearing against him but failed to appear, and a default order was entered.	No	Certificate of Registration No. CS08932 and DV00496 is forfeited, and the Order is a public reprimand. Respondent fined $5,000; and assessed $2,128.50 in attorney's fees and costs.	N/A

MH failed to submit proof of completion of the required thirty continuing education credits to the Board for her biannual renewal period from November 1, 2021, and October 31, 2023. The respondent failed to appear for her December 4, 2024, Board hearing, and a default order was entered against her.	No	Certificate of Registration No. 09550 is revoked with an allowance to petition for reinstatement after one year. Respondent ordered to reimburse the Board for attorney's fees and costs in the amount of $500.	N/A

5A

FILED
OCT 10 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **SUSAN M. BELL, APRN,** **Certificate of Registration No. CS23773,** **Respondent.**	**Case No. 21-084-CS-S** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Susan M. Bell, APRN, Certificate of Registration No. CS23773, is hereby directed to appear before the Board for a hearing to show cause scheduled for **January 15, 2025, at 9:00AM PST** at the following location:

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

2. On December 1, 2022, the Board entered default against Respondent pursuant to NRS 622A.320(1), NRS 639.244 and NRS 622A.350, and entered its Findings of Fact, Conclusions of (Default Order).

3. Respondent has failed to make payment of a fine of Five Thousand Dollars ($5,000) pursuant to the Default Order.

4. Respondent has failed to make payment of Five Hundred and Forty-Two Dollars and Forty-Five Cents ($542.45) for attorney's fees and investigative costs pursuant to the Default Order.

5. Respondent is therefore directed to show cause why her Certificate of Registration No. CS23773 should not be subject to further discipline pursuant to NRS Chapter 639, or otherwise demonstrate that her conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 10th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Susan Bell
[redacted]
Leavenworth, WA [redacted]

Susan Bell
[redacted]
Henderson, NV [redacted]

Susan Bell
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of December 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Susan Bell
[redacted]
Wenatchee, WA [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN M. BELL, APRN,** **Certificate of Registration No. CS23773,** **Respondent.**	**Case No. 21-084-CS-S** **FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND ORDER**

This matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Wednesday, November 30, 2022, in Las Vegas, Nevada. Courtney K. Lee, Esq., appeared on behalf of Petitioner Board. Respondent Susan M. Bell, APRN ("Bell"), Certificate of Registration No. CS23773, did not appear. The Board found, upon an offer of proof of service, that Respondent Bell was properly served and legally noticed with the Notice and Intended Action and Accusation, but did not file an answer. Further, the Board found, upon an offer of proof of service, that Respondent Bell was properly served and legally noticed with the hearing. Therefore, the Board accepted the allegations against Respondent Bell in the Accusation as true pursuant to NRS 622A.350. Upon default hearing of the case, and also based upon the evidence presented, the Board determined the following Findings of Facts, Conclusions of Law, and Order ("Order").

FINDINGS OF FACTS

The allegations against Respondent, as stated in the Notice of Intended Action and Accusation ("Accusation") on file herein, and upon which the Board determined findings of facts, are as follows:

1. The Board has jurisdiction over Respondent because at the time of the events alleged herein, Respondent Bell held or later renewed a controlled substance registration, Certification of Registration No. CS23773, Certificate of Registration No. CS23773, with the Board.

2. Respondent Bell owns/operates a medical practice called Silver Bullet Anti-Aging and Wellness located 1452 W. Horizon Ridge Parkway, #239, Henderson, Nevada 89012.

3. On or about June 1, 2021, the Board's Compliance Coordinator received a telephone call from Respondent Bell inquiring about the status of her controlled substance registration.

4. Upon investigation, it was discovered that Respondent Bell's controlled registration was expired or non-renewed as of October 31, 2020.

5. On June 1, 2021, Respondent Bell renewed her controlled substance registration. However, from November 1, 2020 through May 31, 2021, she did not have an active controlled substance registration.

6. The Nevada Prescription Monitoring Program ("PMP") was queried by Board's staff from November 1, 2020 through May 31, 2021 which reported that Respondent Bell had prescribed 105 controlled substance prescriptions, including refills, for 30 unique patients.

7. A sampling of controlled substance prescriptions prescribed by Respondent Bell while she did not hold an active controlled substance registration were as follows:

a. On November 20, 2020, a prescription for patient T.G. was issued for testosterone cypionate (sesame) 200 mg/ml injection;

b. On November 23, 2020, a prescription for patient J.H. was issued for testosterone cypionate (sesame) 200 mg/ml injection;

c. On November 25, 2020, a prescription for patient M.L. was issued for depo-testosterone 200 mg/ml injection;

d. On May 3, 2021, a prescription for patient M.L was issued for Oxandrolone capsules 50 mg;

e. On May 3, 2021, a prescription for patient J.W. was issued for phentermine tablets 37.5 mg; and

f. On May 17, 2021, a prescription for patient T.H. was issued for testosterone cypionate (sesame) 200 mg/ml injection.

CONCLUSIONS OF LAW

Based upon the foregoing findings of facts, the Board concludes as a matter of law, that:

8. Respondent Bell, by prescribing controlled substance prescriptions without the required controlled substance registration in violation of NRS 453.225 and NRS 639.2351, Respondent Bell performed her duties as a former and current holder of a controlled substance registration in an incompetent, unskillful, or negligent manner pursuant to NAC 639.945(1)(i) by negligently failing to obtain registration, or failing to confirm registration, prior to prescribing controlled substance medications, and are grounds for suspension or revocation of any license or registration issued by the Board pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

9. Respondent Bell, by prescribing controlled substance prescriptions without the required controlled substance registration in violation of NRS 453.226 and NRS 639.2351, Respondent Bell engaged in unprofessional conduct or conduct contrary to the public interest in violation of NAC 639.945(1)(k) for the unlicensed/unregistered activity, and is subject to

discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210(4), and (12), and/or NRS 639.255.

ORDER

THEREFORE, BASED UPON THE FINDINGS OF FACTS, AND CONCLUSIONS OF LAW, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. Respondent Susan M. Bell, APRN, Certificate of Registration No. CS23773, shall pay fines of Five Thousand Dollars ($5,000) for the violations by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of Order.

2. Respondent Susan M. Bell, APRN shall pay attorney's fees and investigative costs of Five Hundred and Forty-Two Dollars and Forty-Five Cents ($542.45) by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of Order.

3. This Order shall be a public record pursuant to NRS 622.330, and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r-2 and 45 CFR Part 60.

4. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next scheduled Board meeting for

hearing. If the show cause hearing results in a finding of a violation of this Order by Respondent, then the Board may impose additional discipline upon any Respondent consistent with NRS Chapter 639.

5. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 19th day of December, 2022.

Helen Park, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of December 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Susan Bell
[redacted]
Las Vegas, NV [redacted]

9171 9690 0935 0279 3113 61

KRISTOPHER MANGOSING

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN M. BELL, APRN,** **Certificate of Registration No. CS23773,** **Respondent.**	**Case No. 21-084-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Susan M. Bell, APRN ("Bell"), held or later renewed a controlled substance registration, Certification of Registration No. CS23773, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent Bell owns/operates a medical practice called Silver Bullet Anti-Aging and Wellness located at 1452 W. Horizon Ridge Parkway, #239, Henderson, Nevada 89012.

3. On or about June 1, 2021, the Board's Compliance Coordinator received a telephone call from Respondent Bell inquiring about the status of her controlled substance registration.

4. Upon investigation, it was discovered that Respondent Bell's controlled registration was expired or non-renewed as of October 31, 2020.

5. On June 1, 2021, Respondent Bell renewed her controlled substance registration. However, from November 1, 2020 through May 31, 2021, she did not have an active controlled substance registration.

6. The Nevada Prescription Monitoring Program ("PMP") was queried by Board staff from November 1, 2020 through May 31, 2021 which reported that Respondent Bell had prescribed 105 controlled substance prescriptions, including refills, for 30 unique patients.

7. A sampling of controlled substance prescriptions prescribed by Respondent Bell while she did not hold an active controlled substance registration were as follows:

a. On November 20, 2020, a prescription for patient T.G. was issued for testosterone cypionate (sesame) 200 mg/ml injection;

b. On November 23, 2020, a prescription for patient J.H. was issued for testosterone cypionate (sesame) 200 mg/ml injection;

c. On November 25, 2020, a prescription for patient M.L. was issued for depo-testosterone 200 mg/ml injection;

d. On May 3, 2021, a prescription for patient M.L was issued for Oxandrolone capsules 50 mg;

e. On May 3, 2021, a prescription for patient J.W. was issued for phentermine tablets 37.5 mg; and

f. On May 17, 2021, a prescription for patient T.H. was issued for testosterone cypionate (sesame) 200 mg/ml injection.

APPLICABLE LAW

8. An advanced practice registered nurse ("APRN") may prescribe controlled substances if the APRN is authorized to do so by the State Board of Nursing and applies for and pays a fee to obtain a certificate from the Board of Pharmacy. NRS 453.226; NRS 639.2351.

9. A person who dispenses controlled substances and fails to register is guilty of a felony. NRS 453.232.

10. As a holder of a controlled substance registration, it is unprofessional conduct or conduct contrary to the public interest to perform her duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

11. As a holder of a controlled substance registration, it is unprofessional conduct or conduct contrary to the public interest to perform any act, task, or operation for which licensure, certification, or registration is required without the licensure, certification, or registration. NAC 639.945(1)(k).

12. Respondent is subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

COUNT ONE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Conduct

13. By prescribing controlled substance prescriptions without the required controlled substance registration in violation of NRS 453.225 and NRS 639.2351, Respondent Bell performed her duties as a former and current holder of a controlled substance registration in an incompetent, unskillful, or negligent manner pursuant to NAC 639.945(1)(i) by negligently failing to obtain registration, or failing to confirm registration, prior to prescribing controlled substance medications, and are grounds for suspension or revocation of any license or registration issued by the Board pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

COUNT TWO

Unprofessional Conduct - Unlicensed/Unregistered Activity

14. By prescribing controlled substance prescriptions without the required controlled substance registration in violation of NRS 453.226 and NRS 639.2351, Respondent Bell engaged in unprofessional conduct or conduct contrary to the public interest in violation of NAC

639.945(1)(k) for the unlicensed/unregistered activity, and is subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210(4), and (12), and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

DATED this 2nd day of May, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN M. BELL, APRN,** **Certificate of Registration No. CS23773,** **Respondent.**	**CASE NO. 21-084-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 7, 2022, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of May 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN M. BELL, APRN,** **Certificate of Registration No. CS23773,** **Respondent.**	**Case NO. 21-084-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____

SUSAN M. BELL, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of May, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Susan M. Bell
[redacted]
Las Vegas, NV [redacted]

Susan M. Bell
[redacted]
Henderson, NV [redacted]

Darlene Nases
DARLENE NASES

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. LAS VEGAS SCRIPTS RX, Pharmacy License No. PH03930, NATHAN EDOUARD, RPH, Certificate of Registration No. 19462, and SHERMAN WASHINGTON, MD, Certificate of Registration No. CS24310, Respondents.	CASE NOS. 19-243-PH-S 19-243-RPH-S 19-243-CS-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Las Vegas Scripts Rx ("LV Scripts") held a Nevada Pharmacy License No. PH03930, Respondent Nathan Edouard, RPh, ("Edouard") held a Nevada Pharmacist Certificate of Registration No. 19462, and Respondent Sherman Washington, MD, ("Washington") held a Controlled Substance Registration No. CS24310, all issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent LV Scripts is a pharmacy located at 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription. The ingredients and percentages of each drug were not identified on the prescription label.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts was shipping prescriptions to California and Arizona where LV Scripts is not licensed.

b. LV Scripts appeared to be filling faxed prescriptions that were not signed by practitioners, but contained copied signatures.

c. LV Scripts did not include the required documentation on prescriptions received by telephone from practitioners. The prescriptions also lacked the name(s) of the person(s) who telephoned the prescription, the date(s) the prescription(s) were received and/or the name(s) of the pharmacist(s) who received the order(s).

d. LV Scripts is providing pre-printed prescription forms for marketing purposes in efforts to promote sales to patients and/or practitioners.

e. Respondent Eduoard was improperly documenting prescriptions received by telephone orders on transferred prescriptions.

APPLICABLE LAW

7. A pharmacy must be managed by a registered pharmacist who is responsible for compliance by the pharmacy and personnel with all state, and federal laws and regulations regarding the operation of the pharmacy. NRS 639.220(1).

8. Unprofessional conduct includes a licensee failing strictly to follow the instructions of the prescribing practitioner in filling of and/or placing contents on the label of the prescription. NRS 585.485(2)(b)(1); NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

9. Unprofessional conduct includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

10. Unprofessional conduct includes a licensee performing any act, task, or operation for which licensure, certification, or registration is required without the required licensure, certification, or registration. NAC 639.945(1)(k).

11. Unprofessional conduct includes the use of secret formulas and failure to strictly follow the instructions of the person writing, making, or ordering a prescription, and to specify the content on the label of the prescription. NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

12. No pharmacist or owner of a pharmacy may offer an unearned rebate. The furnishing to a practitioner by a pharmacist or pharmacy of prescription blanks bearing the name and address of the pharmacy is an unearned rebate. NRS 639.264.

13. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230; NAC 639.702; NAC 639.945.

14. Respondents are subject to discipline for violations pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

COUNT ONE

Unprofessional Conduct – Failure to Strictly Follow Instructions of Prescribing Practitioner (Respondent Edouard)

15. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful and Negligent Conduct (Respondents Edouard and Washington)

16. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

17. Respondent Washington engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he allowed his copied signature to be used on prescriptions in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

COUNT THREE

Failure to Properly Document Prescriptions on Telephoned Orders (Respondent Edouard)

18. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.707(1), (2), and (6)(b), and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

COUNT FOUR

Unprofessional Conduct – Utilization of Pre-printed Forms as Unearned Rebate (Respondent Edouard)

19. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT FIVE

Unprofessional Conduct – Unlicensed Activity (Respondent Edouard)

20. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he shipped prescriptions to California and Arizona without valid licenses in those jurisdictions in violation of NAC 639.945(1)(k), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT SIX

Pharmacy/Pharmacy Owner Responsibility (Respondent LV Scripts)

21. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license(s)/registration(s) of these Respondents.

Signed this 26th day of APRIL 2022.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**CASE NO. 19-243-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 1, 2022, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of April, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. SHERMAN WASHINGTON, MD, Certificate of Registration No. CS24310, Respondent.	CASE NO. 19-243-CS-S ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____

SHERMAN WASHINGTON, MD,

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of April 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sherman Washington, MD
4966 S. Rainbow Blvd. Suite 100
Las Vegas, NV 89118

Sherman Washington, MD
Transforming Arts
2906 N. Green Valley Pkwy., Suite 114
Henderson, NV 89014

Sherman Washington, MD
1820 E Lake Mead Blvd Ste M
North Las Vegas, NV 89030

Nathan Edouard, RPH
2920 N. Green Valley Pkw Bldg. 8 Ste# 814
Henderson, NV 89014

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy #814
Henderson, NV 89014



SHIRLEY HUNTING

FILED
APR - 7 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case No. 21-104-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sherman Washington, MD, held a controlled substance registration, Certificate of Registration No. CS24310, issued by the Board.

FACTUAL ALLEGATIONS

2. While Respondent was the medical director of Revenge MD, located at 10605 Double R Blvd. in Reno, Script #1287 from Respondent's prescription pad for Revenge MD was pre-signed by Respondent, photocopied and used repeatedly by Respondent and/or Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue the following controlled substance prescriptions for patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary:

A. Patient D.S. - DOB [redacted]
Rx#171143 37.5 MG Phentermine
Rx#171144 500 MG Metformin
Issued and dispensed on 6/25/2021

B. Patient J.A.B. - DOB [redacted]
Rx#171806 37.5 MG Phentermine
Rx#171807 500 MG Metformin
Issued and dispensed on 7/02/2021

C. Patient M.G. - DOB [redacted]
Rx#171460 37.5 MG Phentermine
Issued on 6/29/2021 - not dispensed

D. Patient J.W. - DOB [redacted]
Rx#170879 37.5 MG Phentermine
Rx#170880 500 MG Metformin
Issued and dispensed on 6/21/2021

E. Patient J.H. - DOB [redacted]
Rx#170482 37.5 MG Phentermine
Rx#170483 500 MG Metformin
Issued and dispensed on 6/18/2021

F. Patient T.S. - DOB [redacted]
Rx#171145 37.5 MG Phentermine
Rx#171146 500 MG Metformin
Issued and dispensed on 6/25/2021

G. Patient L.B. - DOB [redacted]
Rx#170711 37.5 MG Phentermine
Rx#170712 500 MG Metformin
Issued and dispensed on 6/21/2021

H. Patient M.Z. - DOB [redacted]
Rx#171101 37.5 MG Phentermine
Rx#171102 500 MG Metformin
Issued and dispensed on 6/25/2021

I. Patient S.M. - DOB [redacted]
Rx#170480 37.5 MG Phentermine
Rx#170481 500 MG Metformin
Issued and dispensed on 6/18/2021

J. Patient E.L. - DOB [redacted] or [redacted]
Rx#172773 37.5 MG Phentermine
Rx#172774 500 MG Metformin
Issued and dispensed on 07/16/2021

K. Patient J.C. - DOB [redacted]
Rx#172318 37.5 MG Phentermine
Rx#172323 500 MG Metformin
Issued and dispensed on 7/09/2021

L. Patient L.Y. - DOB [redacted]
Rx#172283 37.5 MG Phentermine
Rx#172284 500 MG Metformin
Issued and dispensed on 7/9/2021

M. Patient N.K. - DOB [redacted]
Rx#171068 37.5 MG Phentermine
Rx#171070 500 MG Metformin
Issued and dispensed on 6/25/2021

N. Patient M.M. - DOB [redacted]
37.5 MG Phentermine
500 MG Metformin
Pharmacy declined to fill

3. Respondent failed to query the Prescription Monitoring Program (PMP) database between November 16, 2020, and January 19, 2022.

4. On his 2020 biennial renewal application for Certificate of Registration No. CS24310, Respondent failed to disclose to the Board recent administrative actions against him, including, without limitation:

- Arizona Medical Board – Case No. MD-19-1137-A (reprimand/probation)
- State Medical Board of Ohio – Case No. 35.123613 (license revocation)
- Colorado Medical Board – Case No. 2019-8449-B (letter of admonition)
- Georgia Composite Medical Board – Case No. 20220043 (fine)
- Virginia Board of Medicine – Case No. 187506 (license suspension)
- Pennsylvania State Board of Medicine – Case No. 19-49-017073 (reprimand)
- Washington Medical Commission – Case No. W2019-234 (license suspension)
- North Dakota Board of Medicine – Case No. 11222019 (conditions placed on license)

5. On or about December 3, 2021, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 21-41427-1, and placed Respondent's License No. 15168 to practice medicine on probation for engaging in conduct in violation of the standards of practice established by the NSBME, specifically for violation of NRS 630.306(1)((b)(3)) related to engaging in conduct that violates Board regulations, and violation of NRS 630.3062(1)(h), related to the fraudulent, illegal, unauthorized or otherwise inappropriate prescribing, administering or dispensing of a controlled substance listed in schedule II, III or IV, while Respondent was the medical director of Vida Spa, located at 3225 S Rainbow Blvd. #107 and or #206 in Las Vegas.

6. As detailed in the NSBME's order in Case No. 21-41427-1, Respondent permitted persons not licensed as practitioners in Nevada to act under his authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary.

APPLICABLE LAW

7. No person may possess, administer, furnish, prescribe or dispense a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.232; NRS 453.321(1)(a); NRS 453.377; NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

8. No person may possess, administer furnish, prescribe or dispense a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321; NRS 454.356; NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

9. No person may possess, administer furnish, prescribe or dispense a hypodermic device except as authorized by law. NRS 454.480; NRS 454.510; NRS 454.530.

10. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1).

11. A prescription for a controlled substance may be issued only for a legitimate medical purpose and after review of a patient's utilization report in the Prescription Monitoring Program (PMP) database in conformance with NRS 639.23507. 21 CFR § 1306.04(a); NRS 453.381(1).

12. It is a felony offense to falsify a prescription for a controlled substance, falsely representing oneself as a practitioner entitled to write prescriptions, or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.331(1)(c), (d), (f), (h) and (i); NRS 639.281(1); NRS 639.2813(1).

13. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

14. A licensed practitioner who wishes to dispense controlled substances or dangerous drugs must register with the Board. NRS 453.226(1); NRS 454.215(3); NRS 454.356; NRS 639.100(1); NRS 639.23505; NAC 639.742.

15. All controlled substances and dangerous drugs in the possession of a practitioner must be kept in a locked storage area with access restricted to authorized persons. 21 CFR § 1301.71; NAC 453.400; NAC 453.410(1)(d).

16. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

17. NRS 453.164(7) requires each practitioner to review his or her prescriber activity in the Prescription Monitoring Program (PMP) database at least once every 6 months.

18. Supplying or diverting drugs or devices which are legally sold in pharmacies so that unqualified persons can circumvent any law pertaining to the legal sale of such articles constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

20. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person not licensed to practice in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

23. Prescribing or dispensing a drug to any patient with whom the prescribing or dispensing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

24. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

25. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

26. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

27. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

28. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

29. By fraudulently issuing controlled substance prescriptions as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

30. By fraudulently issuing controlled substance prescriptions as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1) and/or NRS 639.235(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of State Law - Prescription Monitoring Program

31. By failing to query the Prescription Monitoring Program (PMP) database between November 16, 2020, and January 19, 2022, to review a patient's utilization report prior to issuing a prescription for a controlled substance and to review his prescriber activity, as

alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.164(7) and NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT FOUR

Furnishing False Material Information to Board

32. By failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.331(1)(e), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT FIVE

Obtaining Registration by False or Fraudulent Application

33. By failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), and/or NRS 639.210(10).

COUNT SIX

Violation of Federal Controlled Substances Act – Unlawful Operation of Vida Spa

34. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 21-41427-1, and permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances to patients with whom Respondent had not established a *bona fide* therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a controlled substance was medically necessary, Respondent violated, attempted to violate, assisted or abetted in the violation of or

conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT SEVEN

Violation of State Law – Unlawful Operation of Vida Spa

35. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 21-41427-1, and permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a *bona fide* therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS 453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505 and/or NAC 639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Dispensing Without a Valid Registration

36. By dispensing controlled substances and dangerous drugs in the course of operating Vida Spa without a valid dispensing practitioner registration as detailed in the NSBME's order in Case No. 21-41427-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.266(1); NRS 453.321(1)(a); NRS 454.215(3), NRS 454.221, NRS 454.356, NRS 639.100(1), NRS 639.23505 and/or NAC

639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT NINE

Permitting Unrestricted Access to Drug Inventory

37. By permitting persons not licensed as practitioners in Nevada to have unrestricted access to the inventory of controlled substances and dangerous drugs in the course of operating Vida Spa, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71, NAC 453.400 and/or NAC 453.410(1)(d), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT TEN

Unprofessional Conduct – Diversion

38. By permitting Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue controlled substance prescriptions as alleged in paragraph 2 herein, and by permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent supplied and/or diverted drugs or devices which are legally sold in pharmacies so that unqualified persons can circumvent any law pertaining to the legal sale of such articles and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

39. By fraudulently issuing controlled substance prescriptions as alleged in paragraph 2 herein, by failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, and by permitting persons not licensed as

practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWELVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

40. By his acts as alleged herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT THIRTEEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

41. By permitting Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue controlled substance prescriptions as alleged in paragraph 2 herein, and by permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent aided and abetted unlicensed practice and engaged in unprofessional conduct as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FOURTEEN

Unprofessional Conduct – Dispensing without a Valid Registration

42. By dispensing controlled substances and dangerous drugs in the course of operating Vida Spa without a valid dispensing practitioner registration as detailed in the NSBME's order in Case No. 21-41427-1, Respondent engaged in unprofessional conduct and

conduct contrary to the public interest as defined in NAC 639.945(1)(k), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIFTEEN

Unprofessional Conduct – Prescribing/Dispensing Without Bona Fide Therapeutic Relationship

43. By unlawfully prescribing and dispensing controlled substances and dangerous drugs to patients with whom he did not have a bona fide therapeutic relationship as alleged in paragraph 2 herein and as detailed in the NSBME's order in Case No. 21-41427-1, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(n) and (o), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIXTEEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

44. By his acts as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 7th day of March 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**CASE NO. 21-104-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 1, 2022, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of APRIL, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**CASE NO. 21-104-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____

SHERMAN WASHINGTON, MD,

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of April, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sherman Washington, MD
4966 S. Rainbow Blvd. Suite 100
Las Vegas, NV 89118

Sherman Washington, MD
Transforming Arts
2906 N. Green Valley Pkwy., Suite 114
Henderson, NV 89014

Sherman Washington, MD
1820 E Lake Mead Blvd Ste M
North Las Vegas, NV 89030

SHIRLEY HUNTING

FILED
SEP 08 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case Nos. 19-243-CS-S** **21-104-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, by and through counsel, Michael Mee, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about April 7, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 21-104-CS-N together with the Statement to Respondent and Notice of Hearing.

3. On or about April 26, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 19-243-CS-S together with the Statement to Respondent and Notice of Hearing.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged herein, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations plead with particularity in each accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) , 21 CFR § 1306.04(a), NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NAC 454.060, by permitting persons not licensed as practitioners in Nevada to fraudulently issue prescriptions for controlled substances and/or dangerous drugs under Respondent's credentials;

B. Respondent violated NRS 453.164(7) and NRS 639.23507 by failing to query the Prescription Monitoring Program (PMP) database;

C. Respondent violated NRS 453.331(1)(e) by failing to disclose administrative actions to the Board on his 2020 biennial renewal application and on his applications for two additional controlled substance registrations;

D. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a), CFR § 1301.71, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS

453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505, NAC 639.742, NAC 453.400 and/or NAC 453.410(1)(d), in the course of operating Vida Spa as detailed in the Nevada State Board of Medical Examiners' order in Case No. 21-41427-1; and

E. Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), (i), (j), (k), (n) and/or (o); and committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1).

8. In order to resolve Case Nos. 19-243-CS-S and 21-104-CS-N without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The certificate of registration of Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, is hereby revoked pursuant to NRS 453.241(l)(b):

1) Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration.;

2) Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of two (2) years from the effective date of this Order; and

3) In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	600.00
Total	**$5,000.00**

Respondent shall make the monthly payments of the fine amount by personal, business, certified or cashier's check or money order made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

C. Pursuant to NRS 622.400, Respondent shall pay:

1) Six Hundred Dollars ($600.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 19-243-CS-S; and

2) Four Thousand Dollars ($4,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 21-104-CS-N.

Respondent shall pay the attorney's fees and costs through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	200.00
Total	**$4,600.00**

Respondent shall make the monthly payments of the attorney's fees and costs by personal, business, certified or cashier's check or money order made payable to the **"Nevada State Board of Pharmacy"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 8, 2022. Respondent or his counsel will appear at the meeting to answer questions from the Board

Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 2 day of September, 2022

SHERMAN WASHINGTON, MD,
Certificate of Registration No. CS24310

Signed this 2nd day of September, 2022

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT this 2nd day of September, 2022

MICHAEL MEE, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, in Case Nos. 19-243-CS-S and 21-104-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 8th day of September, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Michael Mee, Esq.
3175 E. Warm Springs Rd. Suite #134
Las Vegas, NV 89120

9171 9690 0935 0265 0825 41

KRISTOPHER MANGOSING

FILED
OCT 10 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case Nos. 19-243-CS-S** **21-104-CS-N** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Sherman Washington, MD, revoked Certificate of Registration No. CS24310, is hereby directed to appear before the Board for a hearing to show cause scheduled on **January 15, 2025, at 9:00AM at the following location:**

Hilton Garden Inn South
7830 S Las Vegas Blvd
Las Vegas, NV 89123

2. On September 8, 2022, the Board approved and entered a Stipulation and Order revoking Certificate of Registration No. CS24310 and imposing discipline on Respondent pursuant to NRS 453.241(1)(b) and NRS 639.255.

3. Respondent has failed to make payment of a fine of Five Thousand Dollars ($5,000) pursuant to the Stipulation and Order payment schedule.

4. Respondent has failed to make payment of Four Thousand Six Hundred Dollars ($4,600.00) for recoverable attorney's fees and costs pursuant to the Stipulation Order payment schedule.

5. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapters 453 and 639, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 10th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sherman Washington, MD
1820 E Lake Mead Blvd, Ste M
Las Vegas, NV 89030

Sherman Washington, MD
[redacted]
Las Vegas, NV [redacted]

Sherman Washington, MD
4966 S Rainbow Blvd, Suite 100
Las Vegas, NV 89118

Sherman Washington, MD
[redacted]
North Las Vegas, NV [redacted]

Michael Mee, Esq.
400 S 4th St. #500
Las Vegas, NV 89101

ERIN MILLER
ADMINISTRIVE ASSISTANT –
BOARD COORDINATOR II

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231, and** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**CASE NOS. 22-185-CS-A-S** **22-185-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Samuel Yu, APRN (Yu), held a Nevada controlled substance registration, Certificate of Registration No. CS27231, and Respondent Mee Han (Han), APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS22622, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents served as medical directors of Opus Face N Body Aesthetics (Opus), located at 6850 W Spring Mountain Road #102, in Las Vegas, Nevada, during the relevant times frames herein. Han served as medical director from May 2021 until May 2022 and Yu was appointed medical director May 5, 2022. Mee Kwyung Lee (Lee) owned Opus Face and Body and is not a Nevada-licensed practitioner.

3. A Board investigation in June 2022 revealed that during their respective tenures as medical directors of Opus, Respondents permitted Lee and registered nurses (RNs) at Opus to

have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondents' presence and without Respondents' supervision.

4. The investigation revealed that Respondents permitted RNs at Opus to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at Opus, including the administration of dangerous drugs by injection, specifically cosmetic injectable fillers, including, without limitation, Allergan's Juvederm Voluma, Volift, Vobella with lidocaine, and Botox drug products, without direct practitioner supervision, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

5. The investigation revealed that the dangerous drug products in the inventory of Opus that were furnished and administered to patients were intended for distribution in foreign markets and not approved for distribution or use in the U.S.

6. On or about July 11, 2022, the Board issued a cease and desist order with a citation and fine against Lee pursuant to NRS 639.2895 for unlicensed activity.

APPLICABLE LAW

7. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

8. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

9. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the U.S. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

10. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

11. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

12. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

13. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

14. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

16. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

17. By permitting Lee and RNs to have unrestricted access to their inventory of dangerous drugs at Opus as alleged in paragraph 3 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

18. By permitting RNs to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 4 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and are subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

COUNT THREE

Violation of Federal and State Law – Using Drugs Not Approved in United States

19. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 5 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1)

and/or NRS 585.490, and are subject to discipline pursuant to NAC 639.900(10) and (14) and/or NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

20. By their conduct as alleged in paragraphs 3-5 herein, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their conduct as alleged in paragraphs 3-5 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **Respondent.**	**Case No. 22-185-CS-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **Respondent.**	**Case No. 22-185-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

SAMUEL YU, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Samuel Yu, APRN c/o
Yu & I Wellness Center
6268 S. Rainbow Blvd Ste 100
Las Vegas, NV 89118

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
NOV 04 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**Case No. 22-185-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent Samuel Yu Ph.D. FNP APRN ("Respondent Yu"), in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

   a. Respondent Yu was hired as a medical director in May 2022. As stated in the Medical Director Agreement dated May 5, 2022, one of Respondent Yu's stated duties were to perform remote telehealth services to consult with patients utilizing electronic video communication. As such, he did not physically work inside the clinic located at 68750 W Spring Mountain Rd #102, Las Vegas, Nevada 89146 prior to the June 23, 2022, inspection, but only worked remotely.

b. Respondent Yu was unaware of this Nevada requirement to keep the dangerous drugs independently inaccessible to RNs until the Board inspection of the facility on June 23, 2022.

c. After the Board's inspection on June 23, 2022, when Respondent Yu first became aware of Nevada's locked access requirements, he immediately took steps to ensure that all dangerous drugs were kept in locked storage that only he had access to, that no one could independently access, and he prepared written protocols and guidelines to be followed.

d. Respondent Yu did not authorize the purchase of illegal drugs from non-US entities; this was put into practice by the medical director Mee Han ("Han"), who convinced the owner, Lee, that these practices were legal, when in fact they were not.

e. Respondent Yu was unaware Opus Face and Body ("Opus") was using or purchasing illegal drugs, the owner was also unaware of it because she relied upon Mee Han for this information. Because Respondent Yu was operating remotely as the medical director from May 5, 2022 until June 23, 2022, he was unaware of any of this illegal activity until June 23, 2022, at which time the use of these items ceased.

f. Opus was closed permanently after the June 23, 20222 incident, so no more Opus medical spa business has been operating since then.

g. The accusations fail to distinguish between the actions or inactions of Respondent Yu and Respondent Han, making the accusations appear that Respondent Yu consented to and participated equally and/or jointly in

continuation or furtherance of the illegal and/or improper activities with the prior medical director, Respondent Mee Han.

h. The accusation is incomplete in that it fails to enumerate the things Respondent Yu did after learning about Nevada requirements on June 23, 2022, and the illegal activities of former medical director Han.

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

a. Respondent Yu admits paragraph 1.

b. As to paragraph 2, Respondent Yu does not know the commencement of Han's tenure as medical director therefore denies this part; Respondent Yu admits that Han's tenure continued through May 26, 2022; Respondent Yu and admits that his appointment as medical director was effective on May 5, 2022, and overlapped Han's tenure;

c. Respondent Yu admits this occurred until June 23, 2022. Respondent Yu denies this continued to occur after that date.

d. As to paragraph 3, Respondent Yu admits the allegations occurred until June 23, 2022.

e. As to paragraph 4, Respondent Yu denies all allegations contained therein as to himself, except he admits the RNs had independent access to the dangerous drugs set forth therein until June 23, 2022.

f. As to paragraph 5, Respondent Yu admits that these allegations, up to June 23, 2022.

g. Respondent Yu admits paragraph 6, and also states that Opus has been is permanently closed.

h. As to paragraphs 7 through 16, Respondent Yu does not dispute the express wording of the United States Code ("U.S.C."), the Nevada Revised Statutes ("NRS"), or the Nevada Administrative Code ("NAC") as set forth in these paragraphs but is without sufficient legal knowledge to comment as to their interpretation or application as set forth in this Notice of Intended Action and Accusation, therefore must deny to that extent, and will rely on his attorney for counsel and advice.

i. Respondent Yu denies intentionally or knowingly committing any violations of State or Federal law set forth in paragraphs 17 through 21.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED: 11/4/2024



SAMUEL YU, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the law office of Craig K. Perry & Associates, and that on this 4th day of November, 2024, I served a true and correct copy of the foregoing Answer and Notice of Defense by electronic means by emailing to the following;

Nevada State Board of Pharmacy
Email: TeamBC@pharmacy.nv.gov
Email: bkandt@pharmacy.nv.gov

/s/ Tyrin Kanemeier

TYRIN KANEMEIER
OFFICE MANAGER
CRAIG K. PERRY & ASSOCIATES

5D

FILED
OCT 04 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231, and** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**CASE NOS. 22-185-CS-A-S** **22-185-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Samuel Yu, APRN (Yu), held a Nevada controlled substance registration, Certificate of Registration No. CS27231, and Respondent Mee Han (Han), APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS22622, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents served as medical directors of Opus Face N Body Aesthetics (Opus), located at 6850 W Spring Mountain Road #102, in Las Vegas, Nevada, during the relevant times frames herein. Han served as medical director from May 2021 until May 2022 and Yu was appointed medical director May 5, 2022. Mee Kwyung Lee (Lee) owned Opus Face and Body and is not a Nevada-licensed practitioner.

3. A Board investigation in June 2022 revealed that during their respective tenures as medical directors of Opus, Respondents permitted Lee and registered nurses (RNs) at Opus to

have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondents' presence and without Respondents' supervision.

4. The investigation revealed that Respondents permitted RNs at Opus to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at Opus, including the administration of dangerous drugs by injection, specifically cosmetic injectable fillers, including, without limitation, Allergan's Juvederm Voluma, Volift, Vobella with lidocaine, and Botox drug products, without direct practitioner supervision, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

5. The investigation revealed that the dangerous drug products in the inventory of Opus that were furnished and administered to patients were intended for distribution in foreign markets and not approved for distribution or use in the U.S.

6. On or about July 11, 2022, the Board issued a cease and desist order with a citation and fine against Lee pursuant to NRS 639.2895 for unlicensed activity.

APPLICABLE LAW

7. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

8. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

9. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the U.S. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

10. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

11. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

12. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

13. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

14. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

16. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

17. By permitting Lee and RNs to have unrestricted access to their inventory of dangerous drugs at Opus as alleged in paragraph 3 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

18. By permitting RNs to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 4 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and are subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

COUNT THREE

Violation of Federal and State Law – Using Drugs Not Approved in United States

19. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 5 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1)

and/or NRS 585.490, and are subject to discipline pursuant to NAC 639.900(10) and (14) and/or NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

20. By their conduct as alleged in paragraphs 3-5 herein, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their conduct as alleged in paragraphs 3-5 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondent.**	**Case No. 22-185-CS-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondent.**	**Case No. 22-185-CS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

MEE HAN, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mee Han, APRN c/o
Legacy Women's Health
8480 S Eastern Ave., #F
Las Vegas, NV 89123

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231, and** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**CASE NOS. 22-185-CS-A-S** **22-185-CS-B-S** **STIPULATION AND ORDER** **[RESPONDENT HAN ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Mee Han, APRN, Certificate of Registration No. CS22622, by and through counsel, Kenneth E. Hogan, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about October 4, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is entering into this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act),

NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent contests the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent was engaged to serve as medical director of Opus Face N Body Aesthetics (Opus);

B. Opus owner Mee Kwyung Lee and registered nurses (RNs) had unrestricted access to their inventory of dangerous drugs at Opus, in violation of NAC 639.898(1);

C. RNs at Opus could independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, in violation of NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1); and

D. Opus purchased, possessed, sold, furnished and/or administered drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., in violation of 21 USC § 331, 21 USC § 355(a), NRS 454.351(1) and/or NRS 585.490.

8. Those alleged violations are pled with particularity in the Accusation, and, if proven, are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.255.

9. Respondent has no prior record of discipline with the Board.

10. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The controlled substance registration of Mee Han, APRN, Certificate of Registration No. CS22622, is suspended for a period of one (1) year pursuant to NRS 453.241(1)(a). The suspension is stayed, and Respondent is placed on probation pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding her duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by March 1, 2025;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS22622 will be fully restored.

11. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately suspend Respondent's Certificate of Registration No. CS22622 and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on January 15, 2025. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC. § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 25 day of December 2024

MEE HAN, APRN
Certificate of Registration No. CS22622

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 25 day of December 2024

KENNETH HOGAN, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Mee Han, APRN, Certificate of Registration No. CS22622, in Case No. 22-185-CS-B-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of January 2025.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
OCT 14 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD,** **Certificate of Registration No. CS20182,** **Respondent.**	**Case No. 22-417-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Jeffrey D. Gross, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS20182, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about July 21, 2021, in *United States of America v. Jeffrey David Gross*, United States District Court for the Central District of California, Case 8:18-cr-00014-JLS, Respondent pled guilty to and was convicted on one felony count of conspiracy to violate patients' rights to honest services, in violation of 18 U.S. Code § 371. The conviction resulted from Respondent accepting bribes and/or kickbacks for patient referrals to specific entities for medical care.

APPLICABLE LAW

3. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

4. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

5. Conviction of a felony related to holding a controlled substance registration or any other crime involving moral turpitude, dishonesty or corruption is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(7)(a) and (c).

COUNT ONE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

6. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h) and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO

Felony Convictions for Conspiracy to Violate Patients' Rights to Honest Services

7. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or 639.210(7)(a) and (c).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

8. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent has committed acts that render his Nevada controlled substance

registration inconsistent with the public interest and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 16 day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD** **Certificate of Registration No. CS20182,** **Respondent.**	**Case No. 22-417-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD** **Certificate of Registration No. CS20182,** **Respondent.**	**Case No. 22-417-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JEFFREY D. GROSS, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jeffrey D. Gross, MD c/o
SPINE: Jeffrey Gross, MD
1661 W Horizon Ridge Pkwy, Suite #280
Henderson, NV 89012

Jeffrey D. Gross, MD c/o
Henderson Joint Replacement Center
2779 W Horizon Ridge Pkwy, Suite #200
Henderson, NV 89052

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NOV 14 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD,** **Certificate of Registration No. CS20182,** **Respondent.**	**CASE NO. 22-417-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent Jeffrey D. Gross, MD, hereby responds to the Notice of Intended Action and Accusation ("Accusation") filed by Petitioner, the Nevada State Board of Pharmacy, on October 14, 2024. This response is Respondent's Answer and Notice of Defense pursuant to NRS 639.244.

I

Respondent objects to the Accusation on the following grounds:

1. Respondent requests a hearing in this matter.

2. The Accusation is vague, ambiguous, incomplete, and fails to set forth clearly the charges against Respondent because, *inter alia*:

a. it fails to allege any factual basis for the conclusory assertion in Counts One, Two, and Three that Respondent's continued registration would be inconsistent with the public interest, as determined pursuant to the factors set forth in NRS 453.231(1); and

b. it fails to allege any factual basis for the claim in Count Two that Respondent has been convicted of "[a] felony relating to holding a certificate, license, registration or permit pursuant to [NRS Chapter 639]," NRS 639.210(7)(a).

3. Petitioner has unduly and unreasonably delayed in bringing this action, in violation of Respondent's due process rights.

II

Respondent responds to the allegations in the Accusation as follows:

JURISDICTION

1. Respondent admits the allegations in Paragraph 1.

FACTUAL ALLEGATIONS

2. Respondent admits that Respondent pleaded guilty on August 7, 2020, to one count of conspiracy, in violation of 18 U.S.C. § 371, in Case No. 8:18-cr-00014, in the United States District Court for the Central District of California. Respondent otherwise denies the allegations in Paragraph 2.

APPLICABLE LAW

3. Paragraph 3 states legal conclusions and characterizations to which no response is required. To the extent that a response is required, Respondent denies the allegations.

4. Paragraph 4 states legal conclusions and characterizations to which no response is required. To the extent that a response is required, Respondent denies the allegations.

5. Paragraph 5 states legal conclusions and characterizations to which no response is required. To the extent that a response is required, Respondent denies the allegations.

COUNT ONE

6. Respondent denies the allegations in Paragraph 6 and denies that he is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO

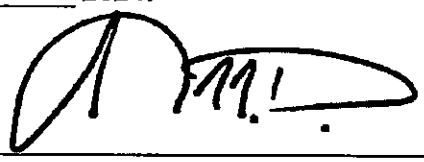
7. Respondent denies the allegations in Paragraph 7 and denies that he is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or 639.210(7)(a) and (c).

COUNT THREE

8. Respondent denies the allegations in Paragraph 8 and denies that he is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 14th day of November 2024.



JEFFREY D. GROSS, MD

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD,** **Certificate of Registration No. CS20182,** **Respondent.**	**CASE NO. 22-417-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, by and through counsel, Ilene Albala, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On October 22, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing by certified mail addressed to Respondent at his last address of record in conformance with NRS 639.242(2).

3. Respondent timely filed an Answer and Notice of Defense to the Accusation on November 14, 2024.

4. Respondent is aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act),

NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent contests the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. On or about August 7, 2020, in *United States of America v. Jeffrey David Gross*, United States District Court for the Central District of California, Case 8:18-cr-00014-JLS, Respondent pled guilty pursuant to a plea agreement and was convicted on one felony count of conspiracy, in violation of 18 U.S. Code § 371; and

B. By his conviction, Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(h), has committed acts that would render his Nevada controlled substance registration inconsistent with the public interest, and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

8. The alleged violations described in Paragraph 7(B) are pled with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.255.

9. On or about October 18, 2024, and subsequent to the filing and service of the Accusation, Respondent surrendered his DEA Registration No. FG3245455 by executing a DEA Form 104, entitled "Surrender for Cause," consistent with the terms of a Memorandum of Agreement with the DEA executed on October 17, 2024. Pursuant to NRS 639.2107, the surrender of DEA Registration No. FG3245455 operated as an immediate suspension of his Certificate of Registration No. CS20182 with the Board, and Respondent is no longer authorized by federal law to dispense controlled substances and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

10. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, stipulate to the following penalties:

A. The certificate of registration of Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, is revoked pursuant to NRS 453.241(1)(b);

B. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance in Nevada until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration;

C. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of one (1) year from the effective date of this Order;

D. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear

before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter;

E. Pursuant to NRS 639.255(1)(f), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00), by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by July 1, 2025; and

F. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by July 1, 2025.

11. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on January 15, 2025. Respondent will appear at the meeting to answer questions from the Board Members and/or

Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein and/or the Notice of Suspension dated November 6, 2024, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 30th **day of** December, **2024**

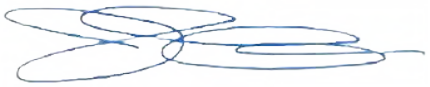


JEFFREY D. GROSS, MD,
Certificate of Registration No. CS20182

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 30th **day of** December **2024**



ILENE ALBALA, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, in Case No. 22-417-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of January 2025.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
OCT 14 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALMART PHARMACY #10-5070, Pharmacy License No. PH01814,** **WILLIAM HERGENROEDER, RPH, Certificate of Registration No. 12708, and** **HERMON BARIAGABR, RPH, Certificate of Registration No. 19456,** **Respondents.**	**Case Nos. 22-537-PH-S** **22-537-RPH-A-S** **22-537-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent William Hergenroeder, RPh (Hergenroeder), Certificate of Registration No. 12708, and Respondent Hermon Bariagabr (Bariagabr), Certificate of Registration No. 19456, were pharmacists registered with the Board. Respondent Walmart Pharmacy #10-5070, Pharmacy License No. PH01814, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Hergenroeder was employed as a managing pharmacist and Bariagabr as a staff pharmacist by Walmart Pharmacy #10-5070, located at 5200 S Ft Apache Road in Las Vegas, at the time of the events alleged herein.

3. On or about December 15, 2022, DVM J.S.'s office called in a prescription for feline patient C.S. to Walmart Pharmacy #10-5070 for 1 vial of Lantus insulin with directions to inject 2 units subcutaneously twice per day with 10 refills. Pharmaceutical technician Haylee Miller performed data entry, erroneously entering directions to inject 24 units subcutaneously, and the Walmart computer system designated this prescription no. 7533967.

4. Hergenroeder performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units subcutaneously.

5. Prescription no. 7533967 was dispensed on December 18, 2022; at that time patient counseling was refused, however, Bariagabr erroneously documented counseling as accepted.

6. C.S. was injected with 24 units that evening and again that morning, went into a hypoglycemic state and experienced negative outcomes requiring medical intervention and treatment by a veterinarian.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Hergenroeder)

7. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

9. Hergenroeder engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units

subcutaneously, resulting in patient harm, and is subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT TWO

Failure to Properly Document Counseling to Patient

(Respondent Bariagabr)

10. A pharmacist shall document medication counseling to a patient when dispensing a prescription in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

11. Bariagabr violated NRS 639.266, NAC 639.707 and/or NAC 639.708 when he failed to properly document medication counseling for prescription no. 7533967, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent Walmart Pharmacy #10-5070)

12. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

13. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walmart Pharmacy #10-5070 is responsible for those violations, including all errors and omissions of Hergenroeder and Bariagabr, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registrations of these Respondents.

Signed this 14th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALMART PHARMACY #10-5070, Pharmacy License No. PH01814,** **Respondent.**	**Case No. 22-537-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALMART PHARMACY #10-5070, Pharmacy License No. PH01814,** **Respondent.**	**Case No. 22-537-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR
Walmart Pharmacy #10-5070

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walmart Pharmacy #10-5070
5200 S Fort Apache Rd
Las Vegas, NV 89148

William J. Hergenroeder, Rph
[redacted]
Las Vegas, NV [redacted]

Hermon Bariagabr, Rph
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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FILED
OCT 14 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALMART PHARMACY #10-5070, Pharmacy License No. PH01814,** **WILLIAM HERGENROEDER, RPH, Certificate of Registration No. 12708, and** **HERMON BARIAGABR, RPH, Certificate of Registration No. 19456,** **Respondents.**	**Case Nos. 22-537-PH-S** **22-537-RPH-A-S** **22-537-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent William Hergenroeder, RPh (Hergenroeder), Certificate of Registration No. 12708, and Respondent Hermon Bariagabr (Bariagabr), Certificate of Registration No. 19456, were pharmacists registered with the Board. Respondent Walmart Pharmacy #10-5070, Pharmacy License No. PH01814, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Hergenroeder was employed as a managing pharmacist and Bariagabr as a staff pharmacist by Walmart Pharmacy #10-5070, located at 5200 S Ft Apache Road in Las Vegas, at the time of the events alleged herein.

3. On or about December 15, 2022, DVM J.S.'s office called in a prescription for feline patient C.S. to Walmart Pharmacy #10-5070 for 1 vial of Lantus insulin with directions to inject 2 units subcutaneously twice per day with 10 refills. Pharmaceutical technician Haylee Miller performed data entry, erroneously entering directions to inject 24 units subcutaneously, and the Walmart computer system designated this prescription no. 7533967.

4. Hergenroeder performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units subcutaneously.

5. Prescription no. 7533967 was dispensed on December 18, 2022; at that time patient counseling was refused, however, Bariagabr erroneously documented counseling as accepted.

6. C.S. was injected with 24 units that evening and again that morning, went into a hypoglycemic state and experienced negative outcomes requiring medical intervention and treatment by a veterinarian.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Hergenroeder)

7. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

9. Hergenroeder engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units

subcutaneously, resulting in patient harm, and is subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT TWO

Failure to Properly Document Counseling to Patient

(Respondent Bariagabr)

10. A pharmacist shall document medication counseling to a patient when dispensing a prescription in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

11. Bariagabr violated NRS 639.266, NAC 639.707 and/or NAC 639.708 when he failed to properly document medication counseling for prescription no. 7533967, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent Walmart Pharmacy #10-5070)

12. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

13. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walmart Pharmacy #10-5070 is responsible for those violations, including all errors and omissions of Hergenroeder and Bariagabr, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registrations of these Respondents.

Signed this 17 day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM HERGENROEDER, RPH,** **Certificate of Registration No. 12708,** **Respondent.**	**Case No. 22-537-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILLIAM HERGENROEDER, RPH,** **Certificate of Registration No. 12708,** **Respondent.**	**Case No. 22-537-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

WILLIAM HERGENROEDER, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walmart Pharmacy #10-5070
5200 S Fort Apache Rd
Las Vegas, NV 89148

William J. Hergenroeder, Rph
[redacted]
Las Vegas, NV [redacted]

Hermon Bariagabr, Rph
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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FILED
OCT 14 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALMART PHARMACY #10-5070, Pharmacy License No. PH01814,** **WILLIAM HERGENROEDER, RPH, Certificate of Registration No. 12708, and** **HERMON BARIAGABR, RPH, Certificate of Registration No. 19456,** **Respondents.**	**Case Nos. 22-537-PH-S** **22-537-RPH-A-S** **22-537-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent William Hergenroeder, RPh (Hergenroeder), Certificate of Registration No. 12708, and Respondent Hermon Bariagabr (Bariagabr), Certificate of Registration No. 19456, were pharmacists registered with the Board. Respondent Walmart Pharmacy #10-5070, Pharmacy License No. PH01814, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Hergenroeder was employed as a managing pharmacist and Bariagabr as a staff pharmacist by Walmart Pharmacy #10-5070, located at 5200 S Ft Apache Road in Las Vegas, at the time of the events alleged herein.

3. On or about December 15, 2022, DVM J.S.'s office called in a prescription for feline patient C.S. to Walmart Pharmacy #10-5070 for 1 vial of Lantus insulin with directions to inject 2 units subcutaneously twice per day with 10 refills. Pharmaceutical technician Haylee Miller performed data entry, erroneously entering directions to inject 24 units subcutaneously, and the Walmart computer system designated this prescription no. 7533967.

4. Hergenroeder performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units subcutaneously.

5. Prescription no. 7533967 was dispensed on December 18, 2022; at that time patient counseling was refused, however, Bariagabr erroneously documented counseling as accepted.

6. C.S. was injected with 24 units that evening and again that morning, went into a hypoglycemic state and experienced negative outcomes requiring medical intervention and treatment by a veterinarian.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Hergenroeder)

7. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

9. Hergenroeder engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed both the four point check of data entry and final verification of prescription no. 7533967 and failed to detect the erroneous direction to inject 24 units

subcutaneously, resulting in patient harm, and is subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT TWO

Failure to Properly Document Counseling to Patient
(Respondent Bariagabr)

10. A pharmacist shall document medication counseling to a patient when dispensing a prescription in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

11. Bariagabr violated NRS 639.266, NAC 639.707 and/or NAC 639.708 when he failed to properly document medication counseling for prescription no. 7533967, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walmart Pharmacy #10-5070)

12. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

13. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walmart Pharmacy #10-5070 is responsible for those violations, including all errors and omissions of Hergenroeder and Bariagabr, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and certificates of registrations of these Respondents.

Signed this 14 day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HERMON BARIAGABR, RPH,** **Certificate of Registration No. 19456,** **Respondent.**	**Case No. 22-537-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HERMON BARIAGABR, RPH,** **Certificate of Registration No. 19456,** **Respondent.**	**Case No. 22-537-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

HERMON BARIAGABR, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walmart Pharmacy #10-5070
5200 S Fort Apache Rd
Las Vegas, NV 89148

William J. Hergenroeder, Rph
[redacted]
Las Vegas, NV [redacted]

Hermon Bariagabr, Rph
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**CASE NO. 24-356-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Safe Chain Solutions, LLC, Nevada Wholesaler License No. WH02131, located in Cambridge, MD, was a wholesaler licensed by the Board.

FACTUAL ALLEGATIONS

2. In March and April 2021, Respondent sold and/or distributed counterfeit drugs purportedly manufactured by Gilead Sciences, Inc. (Gilead), for the treatment of HIV-1 patients, including Biktarvy and Descovy, to no fewer than two pharmacies located in Las Vegas, Nevada, including ASP Cares Pharmacy, Nevada Pharmacy License No. PH03347, and Trinity Pharmacy, Nevada Pharmacy License No. PH03287.

3. Respondent falsified transaction records, including, without limitation, a statement of prior sales, for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead.

4. On or about June 8, 2023, the U.S. Food and Drug Administration (FDA) issued warning letter no. 636044 to Respondent for the sale and/or distribution of counterfeit Biktarvy and other drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act):

> FDA has observed that Safe Chain did not have adequate verification systems in place in violation of section 582(c)(4)(A) & (B) of the FD&C Act. FDA observed that Safe Chain failed to maintain records regarding suspect product investigations in violation of section 582(c)(4)(A)(iii) of the FD&C Act, and failed to respond to a notification of illegitimate product in violation of section 582(c)(4)(B)(iii) of the FD&C Act. In addition, Safe Chain engaged in transactions with unauthorized trading partners in violation of section 582(c)(3) of the FD&C Act. Failure to comply with any of the requirements under section 582 of the FD&C Act is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. § 331(t)).

(SEE EXHBIT A HERETO).

5. On or about September 30, 2024, the Board issued an order to Respondent pursuant to NRS 639.2895 to cease and desist engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead, including Biktarvy and Descovy, into Nevada.

APPLICABLE LAW

6. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain (including wholesale drug distributors) must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

7. A wholesaler must comply with State law when engaging in the sale and/or distribution of drug products into Nevada, including the maintenance of accurate transaction records, including, without limitation, a statement of prior sales identifying each prior sale, purchase, or trade of a drug. NRS 639.595; NAC 639.599; NAC 639.602; NAC 639.603.

8. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or distribute an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460) in Nevada, which shall be deemed a counterfeit drug under NAC 639.605(3)(b). Pursuant to NRS 454.351(1) it is unlawful to sell or distribute any drug which may not be lawfully introduced into interstate commerce under the FD&C Act. Pursuant to NRS 639.550 and NRS 639.555 it is unlawful for a wholesaler to falsify a statement of prior sales for a drug.

10. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

12. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

13. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

COUNT ONE

Violation of Federal Law – Sale/Distribution of Counterfeit Drugs

14. By engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead into Nevada, as alleged herein, Respondent violated 21 U.S.C. § 360eee-1 and/or 21 U.S.C. § 331(a), (b), (c) and/or (t), and is subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law – Sale/Distribution of Counterfeit Drugs

15. By engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead into Nevada, as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2), and/or NRS 639.595, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Law – Falsification of Records

16. By falsifying transaction records, including, without limitation, a statement of prior sales for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead, as alleged herein, Respondent violated 21 U.S.C. § 360eee-1 and/or 21 U.S.C. § 331(a), (b), (c) and/or (t), and is subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violation of State Law – Falsification of Records

17. By falsifying transaction records, including, without limitation, a statement of prior sales for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead, as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.550, NRS 639.555, NAC 639.599, NAC 639.602 and/or NAC 639.603, and is subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

18. By its conduct as alleged herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

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COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

19. By its conduct as alleged herein, Respondent has performed its duties as the holder of a wholesaler license in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of this Respondent.

Signed this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**Case No. 24-356-WH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**Case No. 24-356-WH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR SAFE CHAIN SOLUTIONS, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Safe Chain Solutions
822 Chesapeake Drive
Cambridge, Maryland 21613

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
NOV 27 2024
NEVADA STATE BOARD OF PHARMACY

William J. Stilling (NBN 9915)
STILLING & HARRISON, PLLC
222 S. Main St., Ste. 500
Salt Lake City, Utah 84101
Telephone: 801-341-2021
Facsimile: (801) 341-2021
Email: bstilling@SHhealthlawyers.com

Attorney for Respondent Safe Chain Solutions, LLC

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131** **Respondent.**	**CASE NOS. 24-356-WH0)** **RESPONDENT'S ANSWER AND NOTICE OF DEFENSE**

Respondent Safe Chain Solutions, LLC, by and through its counsel William J. Stilling, of and for Stilling & Harrison, PLLC, answers and provides notice of its defense to the Notice of Intended Action and Accusation ("Notice") in the above-entitled matter and declares as follows.

REQUEST FOR HEARING

Respondent requests a hearing on the Notice.

RESPONSES TO ALLEGATIONS AND CAUSES OF ACTION

In answer to the Notice, Respondent admits, denies, and alleges as follows. Each reference to a "paragraph" is reference to a paragraph in the Notice.

JURISDICTION

1. Respondent admits the allegations in paragraph 1.

FACTUAL ALLEGATIONS

2. Respondent denies the allegations in paragraph 2.

3. Respondent denies the allegations in paragraph 3.

4. Respondent admits that the FDA issued a warning letter on June 8, 2023, and that the document speaks for itself. Respondent does not admit to observations and statements in the warning letter.

5. Without admitting to the statements in the September 30, 2024, Cease & Desist letter, Respondent admits the allegations in paragraph 5. Respondent had previously ceased shipping all Gilead Sciences, Inc. ("Gilead") products as of July 2021. Respondent remains in compliance with the Cease & Desist letter.

APPLICABLE LAW

6. Paragraph 6 is a statement of law and is not susceptible to admission or denial.

7. Paragraph 7 is a statement of law and is not susceptible to admission or denial.

8. Paragraph 8 is a statement of law and is not susceptible to admission or denial.

9. Paragraph 9 is a statement of law and is not susceptible to admission or denial.

10. Paragraph 10 is a statement of law and is not susceptible to admission or denial.

11. Paragraph 11 is a statement of law and is not susceptible to admission or denial.

12. Paragraph 12 is a statement of law and is not susceptible to admission or denial.

13. Paragraph 13 is a statement of law and is not susceptible to admission or denial.

COUNT ONE
Violation of Federal Law - Sale/Distribution of Counterfeit Drugs

14. Respondent denies the allegations in paragraph 14.

15.

COUNT TWO
Violation of State Law - Sale/Distribution of Counterfeit Drugs

16. Respondent denies the allegations in paragraph 15.

COUNT THREE
Violation of Federal Law - Falsification of Records

17. Respondent denies the allegations in paragraph 16.

COUNT FOUR
Violation of State Law - Falsification of Records

18. Respondent denies the allegations in paragraph 17.

COUNT FIVE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

19. Respondent denies the allegations in paragraph 18.

COUNT SIX
Unprofessional Conduct-Incompetent, Unskillfnl or Negligent Performance of Duties

20. Respondent denies the allegations in paragraph 19.

OTHER DEFENSES

21. Counts 1 through 6 fail to state a claim upon which relief can be granted.

22. The factual allegations in the Notice are incomplete and create an impression of wrongdoing by Respondent. Respondent will provide evidence at a hearing that demonstrates Respondent did not engage in wrongdoing. Respondent will also provide evidence that from September 9 through 11, 2024, FDA inspected Respondent's facility in Maryland and that the FDA verbally communicated to Respondent's personnel that based on the inspection the FDA intends to close its case regarding Respondent.

RESERVATION OF RIGHTS

23. Respondent reserves the right to assert other factual, legal, and equitable defenses.

24. Respondent reserves the right to amend this Answer.

OTHER

25. To the extent Respondent has not expressly admitted a factual allegation, it denies all such allegations.

PRAYER FOR RELIEF

26. That the Board dismiss all Causes of Acton in the Notice or that the Board finds that the allegations in the Notice and all evidence presented to the Board do not support imposing discipline on any of the Respondent.

27. That the Board provide further relief to Respondent as it finds just and proper.

DATED this 27th day of November 2024.

William J. Stilling
STILLING & HARRISON, PLLC
Attorneys for Respondents

CERTIFICATE OF SERVICE

I hereby certify that on November 27, 2024, I caused to be served a true and correct copy of the foregoing **ANSWER AND NOTICE OF DEFENSE** by the method indicated below to:

Brett Kandt
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
Nevada State Board of Pharmacy
(bkandt@pharmacy.nv.gov)

- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail

David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
dwuest@pharmacy.nv.gov

- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail



William J. Stilling (NBN 9915)
STILLING & HARRISON, PLLC
222 S. Main St., Ste. 500
Salt Lake City, Utah 84101
Telephone: 801-341-2021
Facsimile: (801) 341-2021
Email: bstilling@SHhealthlawyers.com

Attorney for Respondent Safe Chain Solutions, LLC

FILED
DEC 30 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131** **Respondent.**	**CASE NOS. 24-356-WH0** **RESPONDENT'S AMENDED ANSWER AND NOTICE OF DEFENSE**

Respondent Safe Chain Solutions, LLC, by and through its counsel William J. Stilling, of and for Stilling & Harrison, PLLC, files this Amended Answer and Notice of Defense.

REQUEST FOR HEARING

Respondent requests a hearing on the Notice.

RESPONSES TO ALLEGATIONS AND CAUSES OF ACTION

In answer to the Notice of Intended Action and Accusation, Respondent admits, denies, and alleges as follows. Each reference to a "paragraph" is reference to a paragraph in the Notice.

JURISDICTION

1. Respondent admits the allegations in paragraph 1. Safe Chain is a wholesale pharmaceutical distributor established in 2011 with its headquarters in Cambridge, MD. Safe

Chain provides a wide range of pharmaceuticals and health care products to a diverse network of healthcare facilities nationwide including hospitals, clinics, and surgical centers.

FACTUAL ALLEGATIONS

2. Respondent denies the allegations in paragraph 2.

3. Respondent denies the allegations in paragraph 3. Respondent has never falsified any documents and more specifically has never falsified any documents for products shipped into Nevada.

4. Respondent admits that the FDA issued a warning letter on June 8, 2023, and that the document speaks for itself. Respondent does not admit to observations and statements in the warning letter. A warning letter is not a final action and the assertions in a warning letter are not legally binding conclusions. On June 23, 2023, Safe Chain filed a response to the FDA Warning Letter providing an explanation for each of the observations. Fifteen months later, from September 9 through 11, 2024, the FDA inspected Safe Chain's Maryland facility with a focus on Safe Chain's compliance with the observations raised in the Warning Letter and particularly with verification of trading partners and procedures related to identification of suspect or illegitimate products. At the end of the inspection, the FDA did not communicate any observations of violations to Safe Chain personnel and did not issue an FDA 483 Form.[1] In a conversation between Safe Chain and FDA personnel, FDA personnel explained that it would be issuing a close-out letter. A close-out letter may issue when, based on FDA's evaluation, a company has taken corrective action to address the observations or alleged violations contained in a warning letter.

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[1] An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. *See* FDA Form 483 Frequently Asked Questions at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.

5. Without admitting to the statements in the September 30, 2024, Cease & Desist letter, Respondent admits the allegations in paragraph 5. Respondent had previously ceased shipping all Gilead Sciences, Inc. ("Gilead") products as of July 2021. Respondent remains in compliance with the Cease & Desist letter.

APPLICABLE LAW

6. Paragraph 6 is a statement of law and is not susceptible to admission or denial.

7. Paragraph 7 is a statement of law and is not susceptible to admission or denial.

8. Paragraph 8 is a statement of law and is not susceptible to admission or denial.

9. Paragraph 9 is a statement of law and is not susceptible to admission or denial.

10. Paragraph 10 is a statement of law and is not susceptible to admission or denial.

11. Paragraph 11 is a statement of law and is not susceptible to admission or denial.

12. Paragraph 12 is a statement of law and is not susceptible to admission or denial.

13. Paragraph 13 is a statement of law and is not susceptible to admission or denial.

COUNT ONE
Violation of Federal Law - Sale/Distribution of Counterfeit Drugs

14. Respondent denies the allegations in paragraph 14.

COUNT TWO
Violation of State Law - Sale/Distribution of Counterfeit Drugs

15. Respondent denies the allegations in paragraph 15.

COUNT THREE
Violation of Federal Law - Falsification of Records

16. Respondent denies the allegations in paragraph 16.

COUNT FOUR
Violation of State Law - Falsification of Records

17. Respondent denies the allegations in paragraph 17.

COUNT FIVE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

18. Respondent denies the allegations in paragraph 18.

COUNT SIX
Unprofessional Conduct-Incompetent, Unskillful or Negligent Performance of Duties

19. Respondent denies the allegations in paragraph 19.

OTHER DEFENSES

20. Counts 1 through 6 fail to state a claim upon which relief can be granted.

21. Any cause of action based on allegations of violations of the Food Drug and Cosmetic Act are barred under 21 USC 337(a), which requires "all . . . proceedings for the enforcement, or to restrain violations, of this chapter [Chapter 19] shall be by and in the name of the United States."[2] The FDA has never filed any enforcement action against Safe Chain. Rather, the FDA inspected Safe Chain's Maryland facility September 9 through 11, 2024 with a focus on compliance with provisions of the Food Drug and Cosmetic Act sections referenced in paragraph 4 of the Notice and the FDA did not inform Safe Chain of any observations of violations via an FDA Form 483 or otherwise. Moreover, Nevada has never conducted an inspection of Safe Chain's facility.

22. The Notice fails to plead the specific acts of fraud or deceit with the specificity necessary to defend the allegations.

RESERVATION OF RIGHTS

23. Respondent reserves the right to assert other factual, legal, and equitable defenses.

24. Respondent reserves the right to amend this Answer.

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[2] Chapter 19 of the FDCA contains the laws governing food (Subchapter IV), drugs and devices (Subchapter V), and cosmetics (Subchapter VI). 21 U.S.C. § 337(b) provides exceptions under which a State may bring proceedings in its own name for civil enforcement of certain provisions of Chapter 19, Subchapter IV that govern foods.

OTHER

25. To the extent Respondent has not expressly admitted a factual allegation, it denies all such allegations.

PRAYER FOR RELIEF

26. That the Board dismiss all Causes of Acton in the Notice or that the Board finds that the allegations in the Notice and all evidence presented to the Board do not support imposing discipline on the Respondent.

27. That the Board provide further relief to Respondent as it finds just and proper.

DATED this 30th day of December 2024.

William J. Stilling
STILLING & HARRISON, PLLC
Attorneys for Respondents
Safe Chain Solutions, LLC

CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2024, I caused to be served a true and correct copy of the foregoing **AMENDED ANSWER AND NOTICE OF DEFENSE** by the method indicated below to:

Brett Kandt
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
Nevada State Board of Pharmacy
(bkandt@pharmacy.nv.gov)

- ☐ U.S. Mail postage prepaid
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- ☐ Facsimile
- ☑ Electronic Mail

David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
dwuest@pharmacy.nv.gov

- ☐ U.S. Mail postage prepaid
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- ☐ Facsimile
- ☑ Electronic Mail



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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **JOHN TIMOTHY KATZEN, M.D., Respondent.**	**Case No. 24-34676-1**

FILED
SEP 13 2024
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Alexander J. Hinman, Deputy General Counsel for the Board and attorney for the IC, and John Timothy Katzen, M.D. (Respondent), a licensed physician in Nevada, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on June 23, 2014 (License No. 15386).

2. On June 28, 2024, in Case No. 24-34676-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges one (1) violation of NRS 630.301(3), Disciplinary Action by Another Licensing Board (Count I). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

/ / /

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

3. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

4. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

5. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

6. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is not represented by counsel, and wishes to resolve the matters addressed herein without counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to forgo a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly, and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly, and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I, violation of NRS 630.301(3), Disciplinary Action by Another Licensing Board.

b. Respondent shall immediately cease the practice of medicine and immediately, voluntarily, surrender his license to practice medicine within the State of Nevada pursuant to NAC 630.240.

c. Respondent shall not reinstate or reapply for licensure within the State of Nevada prior to September 13, 2027.

d. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter in the amount of six hundred sixty-seven dollars and ninety-eight cents ($667.98), within ninety (90) days of the Board's acceptance, adoption, and approval of this Agreement.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. Any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

/ / /

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

h. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

6. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

7. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed

and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

8. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

9. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

10. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

11. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

12. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Alexander J. Hinman

ALEXANDER J. HINMAN
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: ahinman@medboard.nv.gov
Attorney for the Investigative Committee

AGREED TO AND UNDERSTOOD.

DATED this 9 day of AUGUST, 2024.

By: John Timothy Katzen M.D

JOHN TIMOTHY KATZEN, M.D.
License No. 15386

SUBSCRIBED and SWORN to before me by John Timothy Katzen, M.D. this _____ day of _____, 2024.

_____
NOTARY PUBLIC

PLEASE SEE THE ATTACHED UPDATED NOTARIAL CERTIFICATE A.O. 08/09/2024 A.O.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

08pgs

SETTLEMENT AGREEMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 9TH day of AUGUST, 2024, by JOHN TIMOTHY KATZENE,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ARGELIA ORTIZ
Notary Public · California
Los Angeles County
Commission # 2346628
My Comm. Expires Feb 12, 2025

(Seal)

Signature Argelia Ortiz

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 24-34676-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 13th day of September, 2024.

DATED this 13th day of September, 2024.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 25, 2024

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:

[redacted]@timothykatzenmd.com

John T. Katzen, MD
[redacted]
Las Vegas NV [redacted]

Re: Notice of Suspension of Registration No. CS24228 (Case No. 24-389-CS-S)

Dear Dr. Katzen:

The Nevada State Board of Pharmacy (Board) has been notified that your License No. 15386 to practice medicine has been surrendered to the Nevada State Board of Medical Examiners pursuant to a settlement agreement entered September 13, 2024. Please be advised that pursuant to NRS 639.2107 this operates as an immediate suspension of your Certificate of Registration No. CS24228 with the Board.

You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD,** **Certificate of Registration No. CS24228,** **Respondent.**	**CASE NO. 24-389-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent John T. Katzen, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS24228, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 13, 2024, Respondent surrendered his License No. 15386 to practice medicine to the Nevada State Board of Medical Examiners (NSBME) pursuant to a settlement agreement in Case No. 24-34676-1.

3. On or about September 25, 2024, Board staff served Respondent with notice that the surrender of his NSBME License No. 15386 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS24228 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

4. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

5. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

6. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

7. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Surrender of NSBME License for Cause

8. By his surrender of his NSBME License No. 15386 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

9. As detailed in the NSBME Order entered an order in Case No. 24-34676-1, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 31st day of September 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD** **Certificate of Registration No. CS24228,** **Respondent.**	**Case No. 24-389-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 31st day of SEPTEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD,** **Certificate of Registration No. CS24228,** **Respondent.**	**Case No. 24-389-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JOHN T. KATZEN, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

John T. Katzen, MD
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

November 21, 2024

VIA ELECTRONIC MAIL TO [redacted]

John T. Katzen, MD
[redacted]
Las Vegas NV [redacted]

Re: Board of Pharmacy v. Katzen, MD - Case No. 24-389-CS-S

Dear Dr. Katzen:

This will confirm that pursuant to NAC 639.120(1)(a) the in-person hearing noticed for December 4, 2024, in Las Vegas will be continued and re-noticed for January 15, 2025, based upon your representation that you are scheduled to perform surgery on December 4 in Los Angeles, California. No further continuance will be granted except as provided in NAC 639.120(1)(c).

Please be advised that your Certificate of Registration No. CS24228 with the Board remains suspended pursuant to NRS 639.2107. You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance in Nevada until the Board reinstates your certificate of registration.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**CASE NO. 24-390-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jon Siems, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS09874, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 16, 2024, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 24-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause.

3. On or about September 25, 2024, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

4. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

5. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

6. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

7. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Suspension of NSBME License for Cause

8. By the suspension of his NSBME License No. 9250 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

9. As detailed in the NSBME Order entered an order in Case No. 24-13009-1, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 31st day of September 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 31st day of SEPTEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JON SIEMS, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jon Siems, MD
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jon Siems, MD
[redacted]
Coto de Caza, CA [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**CASE NOS. 24-390-CS-S** **23-449-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jon Siems, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS09874, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 3, 2021, the Nevada State Board of Medical Examiners (NSBME) and Respondent entered a settlement agreement in Case No. 19-13009-1, imposing discipline on Respondent's NSBME License No. 9250 to practice medicine for cause.

3. Respondent failed to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874.

4. On or about December 27, 2022, the NSBME entered an order in Case No. 19-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause.

5. On or about November 9, 2023, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate

suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

6. Respondent issued at least sixty-eight (68) controlled substance prescriptions for thirty-seven (37) unique patients between December 28, 2022, and March 23, 2023, during the suspension of his NSBME License No. 9250 to practice medicine and his Certificate of Registration No. CS09874 with the Board.

7. Respondent regularly permitted medical assistants to use his credentials to forge and issue prescriptions for controlled substances.

8. Respondent's NSBME License No. 9250 to practice medicine was reinstated to active-probation status on December 18, 2023, and his Certificate of Registration No. CS09874 with the Board was reinstated on February 29, 2024.

9. On or about September 16, 2024, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 24-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause a second time.

10. On or about September 25, 2024, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

11. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

12. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

13. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

14. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(1)(a).

15. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

16. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

17. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

18. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

19. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

20. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

21. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

22. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

23. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

24. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Furnishing False Material Information to Board

25. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1) and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

26. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Prescriptions

27. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and/or 21 CFR § 1306.03(a)(1). By permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent further violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and/or 21 CFR § 1306.03(a)(1). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT FOUR

Violations of State Controlled Substances Act – Unlawfully Issuing Prescriptions

28. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1). By permitting medical assistants to usé his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent further violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FIVE

Unprofessional Conduct – Party to Fraudulent or Deceitful Practice or Transaction

29. By permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

30. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, and by permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional

conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing on Suspended Registration

31. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Suspension of NSBME License for Cause

32. By the suspension of his NSBME License No. 9250 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT NINE

Commission of Acts that Render Registration Inconsistent with the Public Interest

33. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, and by unlawfully issuing controlled substance prescriptions as alleged, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 12 day of November 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **23-449-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **23-449-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JON SIEMS, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of November 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jon Siems, MD
[redacted]
Las Vegas, NV [redacted]

Jon Siems, MD
[redacted]
Coto de Caza, CA [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**Case Nos. 24-390-CS-S** **23-449-CS-S** **SECOND AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jon Siems, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS09874, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 3, 2021, the Nevada State Board of Medical Examiners (NSBME) and Respondent entered a settlement agreement in Case No. 19-13009-1, imposing discipline on Respondent's NSBME License No. 9250 to practice medicine for cause.

3. Respondent failed to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874.

4. On or about December 27, 2022, the NSBME entered an order in Case No. 19-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause.

5. On or about November 9, 2023, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

6. Respondent issued at least sixty-eight (68) controlled substance prescriptions for thirty-seven (37) unique patients between December 28, 2022, and March 23, 2023, during the suspension of his NSBME License No. 9250 to practice medicine and his Certificate of Registration No. CS18967 with the Board.

7. Respondent regularly permitted medical assistants to use his credentials to forge and issue prescriptions for controlled substances.

8. Respondent's NSBME License No. 9250 to practice medicine was reinstated to active-probation status on December 18, 2023, and his Certificate of Registration No. CS09874 with the Board was reinstated on February 29, 2024.

9. On or about September 16, 2024, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 24-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause a second time.

10. On or about September 25, 2024, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

11. On or about November 11, 2024, Respondent surrendered his DEA Certificate of Registration No. BS4492512 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

APPLICABLE LAW

12. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

13. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

14. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

15. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

16. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

17. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

18. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

19. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

20. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

21. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

22. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

23. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

24. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

25. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Furnishing False Material Information to Board

26. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

27. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Prescriptions

28. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and/or 21 CFR § 1306.03(a)(1). By permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent further violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and/or 21 CFR § 1306.03(a)(1). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT FOUR

Violations of State Controlled Substances Act – Unlawfully Issuing Prescriptions

29. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1). By permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent further violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FIVE

Unprofessional Conduct – Party to Fraudulent or Deceitful Practice or Transaction

30. By permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and each is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

31. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, and by permitting medical assistants to use his credentials and act under his authority to fraudulently issue prescriptions for controlled substances Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional

conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing on Suspended Registration

32. By issuing controlled substance prescriptions during the suspension of his Certificate of Registration No. CS09874, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Suspension of NSBME License for Cause

33. By the suspension of his NSBME License No. 9250 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT NINE

Commission of Acts that Render Registration Inconsistent with the Public Interest

34. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 19-13009-1 on his 2022 biennial renewal application for Certificate of Registration No. CS09874, and by unlawfully issuing controlled substance prescriptions as alleged, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

COUNT TEN

Surrender of DEA Registration

35. By the surrender of his DEA Registration No. BS4492512 for cause, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 12th day of December 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD** **Certificate of Registration No. CS09874,** **Respondent.**	**Case Nos. 24-390-CS-S** **23-449-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Second Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of December 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **23-449-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Second Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Second Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Second Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JON SIEMS, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jon Siems, MD
[redacted]
Coto de Caza, CA [redacted]

Jon Siems, MD
[redacted]
Las Vegas, NV [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against JON LANE SIEMS, M.D., Respondent.	**Case No. 19-13009-2**

FILED
DEC 03 2021
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Esq., Deputy General Counsel for the Board and attorney for the IC, and Jon Lane Siems, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, David J. Mortensen, Esq., of the law firm of Messner Reeves LLP, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. Background

1. Respondent is a medical doctor licensed by the Board, pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act), to practice medicine in Nevada since December 20, 1999 (License No. 9250).

2. On November 13, 2019, in Case No. 19-13009-2, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. On November 25, 2020, in Case No. 19-13009-2, the IC filed a First Amended Complaint (First Amended Complaint). Specifically, the Complaint alleges a violation of NRS 630.301(4), Count I, Malpractice, and a

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

violation of NRS 630.3062(1)(a), Count II, Failure to Maintain Proper Medical Records. The First Amended Complaint consisted of adding a violation of NRS 630.3065(2)(a), Count III, Knowing or Willful Failure to Comply with a Board Order, for not providing medical records upon request.

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of the Complaint and the First Amended Complaint, has reviewed and understands the Complaint and the First Amended Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaint.

5. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA) applicable to certain regulatory bodies, which is contained in NRS Chapters 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent

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Reno, Nevada 89521
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understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. Terms & Conditions

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent was, and at all times relevant to the Complaint, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board.

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Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing[2] or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit. Respondent is agreeing to resolve this matter to avoid the costs of a hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I Malpractice, a violation of NRS 630.301(4), and Count II, Failure to Maintain Proper Medical Records, a violation of NRS 630.3062(1)(a), of the First Amended Complaint.

b. Respondent's license to practice medicine in the State of Nevada shall be suspended with the suspension to be immediately stayed. Respondent's license shall be subject to suspension upon a term of probation for a period of sixty (60) months from the date of the Board's acceptance, adoption, and approval of this Agreement (Probationary Period). Respondent must complete the following terms and conditions within the Probationary Period and demonstrate compliance to the good faith satisfaction of the Board before or within sixty (60) months, including but not limited to, payment in full of costs and fees imposed, and at that time he may petition the Board to lift the probationary status of his license. If Respondent fails to demonstrate compliance with the terms and conditions of this Agreement, or otherwise violates the terms of

[2] A hearing was held on September 30, 2020, December 10, 2020, and December 11, 2020, in which Respondent participated without counsel.

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this Agreement or the Medical Practice Act, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing on immediate suspension of his license, which hearing will be duly noticed.

c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of this matter in four (4) equal payments of Six Thousand Two Hundred Fifty-Two Dollars and Seventy-Six Cents ($6,252.76), commencing on January 5, 2022, continuing on February 5, 2022, and March 5, 2022, and paid in full on or before April 5, 2022, upon the Board's acceptance, adoption, and approval of this Agreement.

d. For Count I, Respondent shall pay a fine of five thousand dollars ($5,000.00) in four (4) equal payments of One Thousand Two Hundred Fifty Dollars ($1,250.00), commencing on January 5, 2022, continuing on February 5, 2022 and March 5, 2022, and paid in full on or before April 5, 2022, upon the Board's acceptance, adoption, and approval of this Agreement.

e. Respondent shall complete the University of San Diego, Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, and, if recommended by PACE, the Fitness for Duty (FFD) evaluation, pass all of the above to the satisfaction of the Board, and follow all recommendations presented in the report(s) within one year of the Board's approval, at his cost.

f. Respondent shall complete twenty (20) hours of continuing medical education (CME), fourteen (14) of the CME hours related to the subject matter of best practices in Ophthalmologic surgery, and six (6) hours related to the subject matter of maintaining proper medical records, within one (1) year from the date of the Board's acceptance, adoption, and approval of this Agreement. The aforementioned twenty (20) hours of CME shall be in addition to any CME requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada and shall be approved by the Board prior to their completion.

g. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

h. Respondent shall receive a Public Letter of Reprimand.

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i. Count III shall be dismissed with prejudice, and this Agreement shall encompass the resolution of the formal disciplinary case currently before the Board.

6. **Release From Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement, or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement

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an order of the Board, and, pending full compliance with the terms herein, the case shall be closed.

9. Effect of Rejection of Agreement by Board. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. Binding Effect. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. Forum Selection Clause. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. Attorneys' Fees and Costs. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. Failure to Comply With Terms. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

DATED this 29th day of November, 2021.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE, J.D.
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 20 day of Nov, 2021.

MESSNER REEVES LLP

By: _____

DAVID J. MORTENSEN, ESQ.
8945 W. Russell Road, Suite 300
Las Vegas, NV 89148
Tel: (702) 363-5100
Email: dmortensen@messner.com
Attorney for Respondent

DATED this 24th day of November, 2021.

By: _____

JON LANE STEMS, M.D.,
Nevada License No. 9250
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 19-13009-2) was approved and accepted by the Nevada State Board of Medical Examiners on the 3rd day of December, 2021.

DATED this 3rd day of December, 2021.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

VICTOR M. MURO, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee :	$200.00
Convenience Fee :	$10.00
License Number :	CS09874
License Type :	**Controlled Substance**
New Expiration Date :	10/31/2024

Personal Information

First Name : JON

Middle (initial only) :

Last Name : SIEMS

License # : CS09874

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Jon L Siems , MD., PC

Military Address :

Street : 8230 W SAHARA AVE #111

Country : United States

City : LAS VEGAS State : Nevada Zip : 89117

Practice Phone : [redacted] Practice Fax : (XXX) XXX-XXXX

Email Address : [redacted]@siemslasik.com

Sex : Male

Practice License Number: Specialty:

Child Support Information – Check appropriate answer

- (•) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable — ( ) Yes (•) No

Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable — ( ) Yes (•) No

Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? — ( ) Yes (•) No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? ○ Yes ◉ No

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ○ Yes ◉ No

DEA Registration

Document Name	Document Type	Date	Link	Action
No Record Found				

Document Name :

Document Type : NV DEA Certificate

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload | Cancel

Acknowledgement and Declaration

By signing and submitting this renewal application, I certify that: 1. My DEA certificate is CURRENT and reflects my current NV practicing address, and 2. I hold an **active** and **current** Nevada license with my professional licensing board

It is a violation of Nevada Statute to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

Signature : Jon Siems

Date Of Application : 09/13/2022

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2022 to 10/31/2024	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : 63929757142

InvoiceDate : 09/13/2022

Paid

Pay & Submit

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **JON LANE SIEMS, M.D.,** **Respondent.**	**Case No.: 19-13009-2**

FILED

DEC 27 2022

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By:

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Jon L. Siems, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated a Board Order when he did not satisfy all of the conditions contained in the Settlement Agreement he entered into with the IC on November 29, 2021, and which was approved by the Board on December 3, 2021.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 9250). The Board issued his license on December 20, 1999.

2. On November 29, 2021, Respondent entered into a Settlement Agreeement with the IC and the Board approved the agreement on December 3, 2021. *See* **Exhibit 1** (Settlement Agreement and Order).

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Chairman, Chowdhury H. Ashan, M.D., Ph.D., FACC, and Col. Eric D. Wade, USAF (Ret.).

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Reno, Nevada 89521
(775) 688-2559

3. Notably, two (2) of the conditions contained in the Settlement Agreement were for Respondent, Dr. Siems, to unequivocally complete twenty (20) hours of Continued Medical Education (CME) and to complete the Physician Assessment and Clinical Education Program (PACE) within one (1) year of the Board's acceptance, adoption, and approval of the Agreement. The Settlement Agreement was approved and adopted on December 3, 2021, requiring completion of the terms on or before December 3, 2022.

4. Pursuant to the Settlement Agreement and Order, Respondent agreed that his license was suspended, but that the suspension was immediately stayed, thereby subjecting his license to a sixty (60) month term of probation with conditions for continuing the stay of the suspension.

5. As of the writing of this Order on December 27, 2022, Board staff has received no notification that Respondent has enrolled in nor completed either his CMEs or the PACE Program as required by the Settlement Agreement and Order as a condition to continue the stay of the suspension of his license.

6. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with: (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

7. Based on the foregoing, the IC finds that Respondent, Jon L. Siems, M.D., has willfully and knowingly violated his Settlement Agreement and Board Order and is immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1).

ORDER

IT IS HEREBY ORDERED that the License of Jon L. Siems, M.D. (9250) is immediately **SUSPENDED** until further order of the IC or Board, and Respondent is prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

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IT IS FURTHER ORDERED that a hearing on this matter is set for the **13th day of February, 2023, at 9:00 a.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time. *See* NRS 630.326(2).

DATED this 27th day of December, 2022.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against JON LANE SIEMS, M.D., Respondent.	Case No. 19-13009-2

FILED
DEC 03 2021
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Esq., Deputy General Counsel for the Board and attorney for the IC, and Jon Lane Siems, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, David J. Mortensen, Esq., of the law firm of Messner Reeves LLP, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. Background

1. Respondent is a medical doctor licensed by the Board, pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act), to practice medicine in Nevada since December 20, 1999 (License No. 9250).

2. On November 13, 2019, in Case No. 19-13009-2, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. On November 25, 2020, in Case No. 19-13009-2, the IC filed a First Amended Complaint (First Amended Complaint). Specifically, the Complaint alleges a violation of NRS 630.301(4), Count I, Malpractice, and a

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

violation of NRS 630.3062(1)(a), Count II, Failure to Maintain Proper Medical Records. The First Amended Complaint consisted of adding a violation of NRS 630.3065(2)(a), Count III, Knowing or Willful Failure to Comply with a Board Order, for not providing medical records upon request.

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of the Complaint and the First Amended Complaint, has reviewed and understands the Complaint and the First Amended Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaint.

5. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA) applicable to certain regulatory bodies, which is contained in NRS Chapters 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. Terms & Conditions

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent was, and at all times relevant to the Complaint, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board.

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9600 Gateway Drive
Reno, Nevada 89521
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Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing[2] or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit. Respondent is agreeing to resolve this matter to avoid the costs of a hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I Malpractice, a violation of NRS 630.301(4), and Count II, Failure to Maintain Proper Medical Records, a violation of NRS 630.3062(1)(a), of the First Amended Complaint.

b. Respondent's license to practice medicine in the State of Nevada shall be suspended with the suspension to be immediately stayed. Respondent's license shall be subject to suspension upon a term of probation for a period of sixty (60) months from the date of the Board's acceptance, adoption, and approval of this Agreement (Probationary Period). Respondent must complete the following terms and conditions within the Probationary Period and demonstrate compliance to the good faith satisfaction of the Board before or within sixty (60) months, including but not limited to, payment in full of costs and fees imposed, and at that time he may petition the Board to lift the probationary status of his license. If Respondent fails to demonstrate compliance with the terms and conditions of this Agreement, or otherwise violates the terms of

[2] A hearing was held on September 30, 2020, December 10, 2020, and December 11, 2020, in which Respondent participated without counsel.

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Nevada State Board of Medical Examiners
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Reno, Nevada 89521
(775) 688-2559

this Agreement or the Medical Practice Act, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing on immediate suspension of his license, which hearing will be duly noticed.

c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of this matter in four (4) equal payments of Six Thousand Two Hundred Fifty-Two Dollars and Seventy-Six Cents ($6,252.76), commencing on January 5, 2022, continuing on February 5, 2022, and March 5, 2022, and paid in full on or before April 5, 2022, upon the Board's acceptance, adoption, and approval of this Agreement.

d. For Count I, Respondent shall pay a fine of five thousand dollars ($5,000.00) in four (4) equal payments of One Thousand Two Hundred Fifty Dollars ($1,250.00), commencing on January 5, 2022, continuing on February 5, 2022 and March 5, 2022, and paid in full on or before April 5, 2022, upon the Board's acceptance, adoption, and approval of this Agreement.

e. Respondent shall complete the University of San Diego, Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, and, if recommended by PACE, the Fitness for Duty (FFD) evaluation, pass all of the above to the satisfaction of the Board, and follow all recommendations presented in the report(s) within one year of the Board's approval, at his cost.

f. Respondent shall complete twenty (20) hours of continuing medical education (CME), fourteen (14) of the CME hours related to the subject matter of best practices in Ophthalmologic surgery, and six (6) hours related to the subject matter of maintaining proper medical records, within one (1) year from the date of the Board's acceptance, adoption, and approval of this Agreement. The aforementioned twenty (20) hours of CME shall be in addition to any CME requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada and shall be approved by the Board prior to their completion.

g. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

h. Respondent shall receive a Public Letter of Reprimand.

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i. Count III shall be dismissed with prejudice, and this Agreement shall encompass the resolution of the formal disciplinary case currently before the Board.

6. **Release From Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement, or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement

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an order of the Board, and, pending full compliance with the terms herein, the case shall be closed.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply With Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Nevada State Board of Medical Examiners
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Reno, Nevada 89521
(775) 688-2559

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

DATED this 29th day of November, 2021.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE, J.D.
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 20 day of Nov, 2021.

MESSNER REEVES LLP

By: _____

DAVID J. MORTENSEN, ESQ.
8945 W. Russell Road, Suite 300
Las Vegas, NV 89148
Tel: (702) 363-5100
Email: dmortensen@messner.com
Attorney for Respondent

DATED this 24th day of November, 2021.

By: _____

JON LANE SIEMS, M.D.,
Nevada License No. 9250
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 19-13009-2) was approved and accepted by the Nevada State Board of Medical Examiners on the 3rd day of December, 2021.

DATED this 3rd day of December, 2021.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

VICTOR M. MURO, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

November 9, 2023

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: [redacted]@hotmail.com

Jon L. Siems, M.D., P.C.
[redacted]
Las Vegas NV [redacted]

Re: Suspension of Certificate of Registration No. CS09874 (Case No. 23-449-CS-S)

Dear Dr. Siems:

The Nevada State Board of Pharmacy (Board) has determined that your medical license was suspended by the Nevada State Board of Medical Examiners on December 27, 2022.

Please be advised that pursuant to NRS 639.2107 the suspension of your medical license operates as an immediate suspension of your Certificate of Registration No. CS09874 with the Board. You have **not** been and are **not** authorized to prescribe any controlled substances in the state of Nevada. Furthermore, your access to the Nevada Prescription Monitoring Program (PMP) database is terminated effective immediately since you are no longer authorized to access the PMP pursuant to NRS 453.221.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the forgoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 Ext. 132 or gvanderdonck@pharmacy.nv.gov.

Best regards,

Gustaf Vanderdonck
Assistant General Counsel
Nevada State Board of Pharmacy

9171 9690 0935 0307 6311 33

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **JON LANE SIEMS, M.D.,** **Respondent.**	**Case No.: 24-13009-1**

FILED
SEP 16 2024
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Jon Lane Siems, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated a Board Order when he did not satisfy all of the conditions contained in the discipline issued by the Board after adjudication at the Board meeting on December 1, 2023. *See* **Exhibit 1**.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 9250). The Board issued his license on December 20, 1999.

2. On December 27, 2022, in Case No. 19-13009-2, the IC suspended Respondent's license to practice medicine in the State of Nevada pending a show cause hearing regarding the subject of that summary suspension via an Order of Summary Suspension.

3. On January 30, 2023, the IC filed a formal Complaint against Respondent in Case No. 23-13009-1 which facts relate directly back to an Order issued in Case No. 19-13009-2.

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Chairman, Carl N. Williams, Jr., M.D., and Col. Eric D. Wade, USAF (Ret.).

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4. On February 2, 2023, a show cause hearing was held regarding Respondent's suspension.

5. After attempts to serve Respondent with the formal Complaint on a previous date, Respondent was served with the formal Complaint in Case 23-13009-1 on March 3, 2023.

6. On April 13, 2023, a formal hearing was held in Case No. 23-13009-1.

7. On December 1, 2023, the Board adjudicated the matter and found that Respondent did indeed violate the single count of Knowing or Willful Failure to Comply with a Board Order, as provided by NRS 630.3065(2)(a), and imposed discipline.

8. The discipline the Board imposed was a written public reprimand, that Respondent's license be suspended for a period of one (1) year from December 28, 2022 to December 27, 2023, and on December 28, 2023, Respondent's license status shall be reinstated to an active-probation status; Respondent shall complete the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of the Order; that any continuing medical education received for attending the program shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1); and Respondent was required to reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of the Order.

9. Respondent received a deadline of June 1, 2024, to pay the fines and costs in Case No. 23-13009-1.

10. Johnna LaRue, CMBI, Compliance Officer for the Board sent Respondent a letter dated December 19, 2023, containing helpful instructions and deadlines to assist Respondent in complying with the Board Order. *See* **Exhibit 2**.

11. As of today's date, Respondent has not paid the costs in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) and is therefore in violation of the Board's Order.

12. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with: (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

13. Based on the foregoing, the IC finds that Respondent has willfully and knowingly violated the Board Order and is immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1).

ORDER

IT IS HEREBY ORDERED that the License of Jon Lane Siems, M.D. (9250) is immediately **SUSPENDED** until further order of the IC or Board, and Respondent is prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **18th day of October, 2024, at 9:00 a.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, with video conferencing to the Las Vegas office at 325 E. Warm Springs Road, Suite 225, Las Vegas, Nevada 89119 to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time to hold the hearing. *See* NRS 630.326(2).

DATED this 16th day of September, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

BRET W. [illegible]REY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

CERTIFICATE OF SERVICE

I hereby certify that I am employed by the Nevada State Board of Medical Examiners and that on the 16th day of September, 2024, I served a file-stamped copy of the foregoing **ORDER OF SUSPENSION AND NOTICE OF HEARING**, via Fed Ex (priority overnight), postage pre-paid, to the following parties:

JON LANE SIEMS, M.D.
31852 Via Patito
Coto de Caza, CA 92679

Tracking No.: 778618923066

DATED this 16th day of September, 2024.

MEG BYRD
Legal Assistant
Nevada State Board of Medical Examiners

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against JON LANE SIEMS, M.D., Respondent.	**Case No. 23-13009-1**

FILED
DEC 19 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

This case was presented for adjudication and decision before the Nevada State Board of Medical Examiners (Board), during a regularly scheduled Board meeting on December 1, 2023, at 8:40 a.m., (Pacific Standard Time), located at 325 E. Warm Springs Road, Suite 225, Las Vegas, NV 89119, video conferenced to 9600 Gateway Drive, Reno, NV 89521. Jon Lane Siems, M.D., (Respondent), was properly served with a notice of the adjudication, including the date, time and location, and was present and not represented by counsel. The adjudicating members of the Board participating in these Findings of Fact, Conclusions of Law, and Order (FOFCOL) were: Nick M. Spirtos M.D., F.A.C.O.G., Ms. Maggie Arias-Petrel, Ms. Pamela Beal, Irwin B. Simon, M.D., FACS, Joseph Olivarez, P.A.-C, and Jason B. Farnsworth, RRT, MBA. Chricy E. Harris, Esq., Deputy Attorney General, served as legal counsel to the Board.

The Board, having received and read the Complaint and exhibits admitted at the hearing of this matter, the Hearing Officer's Findings and Recommendations[1], and the transcript of the hearing, made its decision pursuant to its authority and provisions of the Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), NRS Chapter 622A, and NRS Chapter 233B, as applicable.

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[1] The Hearing Officer's Findings and Recommendations were prepared by Charles Woodman, Esq., who was appointed as Hearing Officer under NRS 630.106 in this matter and presided over the hearing.

The Board, after due consideration of the record, evidence, and law, and being fully advised in the premises, makes its FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER in this matter, as follows:

FINDINGS OF FACT

I.

Respondent held an Active-Probation license to practice medicine in the State of Nevada issued by the Board from December 3, 2021, until December 27, 2022. An Order for Summary Suspension of Respondent's license was filed on December 27, 2022, served on December 27, 2022, which immediately suspended Respondent's license until a show cause hearing could be held to determine if his medical license would be reinstated during the regular hearing process. On February 2, 2023, a show cause hearing was held at the office of the Nevada State Board of Medical Examiners and the Hearing Officer entered his order during the hearing that continued the suspension of Respondent's medical license throughout the hearing process.

II.

On January 30, 2022, the Investigative Committee filed its formal Complaint in Case No. 23-13009-1, alleging Respondent violated the Medical Practice Act. Respondent was personally served with the Complaint by a USPS Certified mail on March 3, 2023. The Complaint alleges as follows: Count I, a violation of NRS 630.3065(2)(a) Knowing or Willful Failure to Comply with a Board Order.

Respondent did not answer or file a response to the allegations set forth in the Complaint. Pursuant to NAC 630.460(4), the allegations of the Complaint are deemed generally denied if an answer is not filed.

III.

An Early Case Conference was held at the conclusion of the show cause hearing. Donald K. White, Senior Deputy General Counsel was present on behalf of the Investigative Committee (IC) of the Board, with Hearing Officer Charles Woodman, Esq., Respondent participated in the Early Case Conference and show cause hearing but was not represented by an attorney.

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Reno, Nevada 89521
(775) 688-2559

In compliance with NAC 630.465 an Order After Prehearing and Order Confirming Hearing Date was filed March 1, 2023, setting dates for the formal hearing calendared to commence on April 13, 2023, at the Office of the Nevada State Board of Medical Examiners, 9600 Gateway Drive, Reno, Nevada 89521 video conferenced to the Board's Las Vegas Office, located at 325 E. Warm Springs Road, Suite 225, Las Vegas, NV 89119. All documents intended to be introduced as evidence in the case were to be exchanged on or before March 13, 2023. Respondent was served this Order via USPS Certified Mail on March 6, 2023, at his address of record.

IV.

On April 13, 2023, as duly noticed and ordered, a hearing was held before the Hearing Officer to receive evidence and to hear arguments of both parties. Legal counsel for the Investigative Committee, Donald K. White, Senior Deputy General Counsel appeared, along with Respondent, without legal counsel, and Hearing Officer Charles Woodman, Esq. Mr. White presented the IC's case, offered documentary evidence, and presented witness testimony. Exhibits one (1) through (4) from the IC and several of Respondent's exhibits, were marked and admitted into evidence.

The Hearing Officer provided the Synopsis and Analysis of Record, filed May 9, 2023. This matter was scheduled for final adjudication on December 1, 2023, at a regularly scheduled Board meeting.

The notice of the adjudication was sent via USPS Certified Mail on October 30, 2023, and was delivered to Respondent on November 3, 2023, at 10:14 a.m.

A copy of the adjudication materials along with a copy of the Hearing Officer's Synopsis and Analysis of Record were mailed via Fed Ex 2-Day and were delivered to Respondent's address of record on November 10, 2023.

V.

Pursuant to NRS 622A.300(5)(a), the Findings and Recommendations of the Hearing Officer are hereby approved by the Board in their entirety, with modification to the discipline, and

///

are hereby specifically incorporated and made part of this Order by reference and are attached hereto as **Exhibit 1**.

VI.

In accordance with the Synopsis and Analysis of Record, the Board hereby finds that the count set forth in the Complaint, and as recapitulated in Paragraph II above, have been established by a preponderance of the evidence.

VII.

If any of the foregoing Findings of Fact is more properly deemed a Conclusion of Law, it may be so construed.

CONCLUSIONS OF LAW

I.

The Board has jurisdiction over Respondent and the Complaint, and an adjudication of this matter by the Board members as set forth herein is proper.

II.

Respondent was timely and properly served with the Complaint, and all notices and orders in advance of the hearing and adjudication thereon, in accordance with NRS and NAC Chapters 630, NRS Chapters 241, 622A and 233B, and all legal requirements of due process.

III.

With respect to the allegations of the Complaint, the Board concludes that Respondent has violated NRS 630.3065(2)(a) Knowing or Willful Failure to comply with a Board Order, as alleged in Count I. Accordingly, Respondent is subject to discipline pursuant to NRS 630.352.

IV.

The Board finds that, pursuant to NRS 622.400, recovery from Respondent of reasonable attorneys' fees and costs incurred by the Board as part of its investigation and disciplinary proceedings against Respondent is appropriate. The Board has reviewed the Investigative Committee's Memorandum of Costs and Disbursements and Attorneys' Fees, and the Board finds them to be the actual fees and costs incurred by the Board as part of its investigative, administrative and disciplinary proceedings against Respondent, and finds them to be reasonable,

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

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Reno, Nevada 89521
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necessary, and actually incurred based on: (1) the abilities, training, education, experience, professional standing and skill demonstrated by Board staff and attorneys; (2) the character of the work done, its difficulty, its intricacy, its importance, the time and skill required, the responsibility imposed and the prominence and character of the parties where, as in this case, they affected the importance of the litigation; (3) the work actually performed by the Board's attorneys and staff, and the skill, time and attention given to that work; and (4) the product of the work and benefits to the Board and the people of Nevada that were derived therefrom.

V.

If any of the foregoing Conclusions of Law is more properly deemed a Finding of Fact, it may be so construed.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, and good cause appearing therefore,

IT IS HEREBY ORDERED that:

1. Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3065(2)(a), Knowing or Willful Failure to comply with a Board Order.

2. Pursuant to NRS 630.352(4)(e), the Board shall administer a written public reprimand to Respondent.

3. Respondent's license shall be suspended for a period of one year, from December 28, 2022, to December 27, 2023.[2] On December 28, 2023, Respondent's license status shall be reinstated to an Active-Probation status.

4. Pursuant to NRS 630.352(4)(k), Respondent shall complete at the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of this Order. Any aforementioned hours of Continuing Medical

[2] Pursuant to the Board's motion imposing discipline, the one-year suspension imposed upon Respondent shall take into account the time he has been suspended since the Order of Summary Suspension, which was served upon him on December 28, 2022.

Education received for attending the program that is substantially related to PACE shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1).

5. Respondent shall reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of this Order. The Board, and/or its designee, are granted the authority to collect any and all funds due under this Order.

6. Investigation Case Nos. 18-18146, 19-18953, 20-19625, 20-19679, 20-19736, 21-20367, 22-21285, 22-21357, 23-22654, 23-22790, and 23-22844 shall be dismissed with prejudice.

IT IS SO ORDERED.

DATED this 19th day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
President of the Board

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

CERTIFICATION

I certify that the foregoing is the full and true original **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** on file in the office of the Board of Medical Examiners in the matter of **JON LANE SIEMS, M.D.**, Case No. 23-13009-1.

I further certify that Nick M. Spirtos, M.D., F.A.C.O.G., is the President of the Nevada State Board of Medical Examiners and that full force and credit is due to his official acts as such; and that the signature to the foregoing ORDER is the signature of said Nick M. Spirtos, M.D., F.A.C.O.G.

IN WITNESS THEREOF, I have hereunto set my hand in my official capacity as Secretary-Treasurer of the Nevada State Board of Medical Examiners.

DATED this 19th day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Maggie Arias-Petrel

MAGGIE ARIAS-PETREL
Secretary-Treasurer and Public Member of the Board

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS

OF THE STATE OF NEVADA

FILED
MAY - 9 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

In the Matter of Charges and Complaint Against JON L. SIEMS, M.D., Respondent.	Case No.: 23-13009-1 (Case No.:19-13009-2)

SYNOPSIS AND ANALYSIS OF THE RECORD

Hearing Officer Charles B. Woodman, having heard a formal pre-hearing conference, as well as the formal Hearing of this matter, hereby presents the Nevada State Board of Medical Examiners with his formal Analysis of this case. This Analysis is based upon all evidence adduced at the formal Hearing, this Hearing Officer's findings of facts and conclusions of law, which findings include the credibility of the witnesses who gave evidence.

RELEVANT BACKGROUND

This is a combined case as shown in the caption, whereby the Investigative Committee ("IC") of the Board of Medical Examiners of the State of Nevada ("Board") alleged that Dr. Jon Lane Siems, M.D., ("Dr. Siems") failed to comply with the Settlement Agreement he entered into as resolution to Board Case 19-13009-2. The final page of that Settlement Agreement contains the Board's order mandating compliance with the Agreement. A duly noticed formal hearing of the matter was held before the undersigned Hearing Officer on April 13, 2023 at the Northern Nevada office of the Board in Reno. Mr. Donald K. White, Esq., Senior Deputy General Counsel appeared on behalf of the Board's IC. Dr. Siems appeared via videoconference from the Board's Southern Nevada office representing himself in pro se. The matter was duly recorded by a licensed reporter and is a matter of public record.

The formal Complaint in Board Case 23-13009-1 alleges a single count of Knowing or Willful Failure to Comply with a Board Order, a violation of NRS 630.3065(2)(a), which states that:

> The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:
> * * *
> 2. Except as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with:
> (a) A regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician;

More specifically, the IC alleges at paragraphs 8-9 of the Complaint that:

> 8. Respondent [Dr. Siems] knowingly or willfully failed to comply with an order of the Board when he failed to complete 20 hours of CMEs or the PACE Program by or within the deadline he agree to with the Board [in Case 19-13009-2].
> 9. Additionally, the Settlement Agreement [in Case 19-13009-2] that Respondent signed and was subsequently approved by the Board clearly states that Respondent agreed to be placed on stayed suspension and that if he violated any terms of the agreement that the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause hearing.

Accordingly, the two cases are inextricably linked inasmuch as Dr. Siems' alleged violation of the Order at the final page of the Settlement Agreement entered into in Case 19-13009-2 makes up the entirety of the basis for Case 23-13009-1. Further, it appears that the Board may determine to take formal action in both such cases.

At commencement of the formal Hearing of this matter, Dr. Siems was again advised of his right to be represented by counsel, as this Hearing Officer has so advised him in prior proceedings. The Hearing proceeded with Dr. Siems electing to represent himself. See Transcript at page 5 ("T.5").

It is noted very significantly here that the Board has already determined that Dr. Siems "willfully and knowingly violated his Settlement Agreement" via the Board's Order of Suspension And Notice of Hearing filed December 27, 2022. That Order was issued summarily based on evidence proffered by the IC. A duly noticed formal Order to Show

Cause hearing to determine whether that summary suspension should continue was heard before the undersigned on February 2, 2023, with Dr. Siems in attendance, also representing himself at that time. After that hearing and in light of evidence provided by the IC and by Dr. Siems, this Hearing Officer confirmed the suspension pending further decisions by the Board and pending adjudication of the new complaint in Case 23-13009-1. The April 13 hearing was held to formally adjudicate Case 23-13009-1. At the hearing, the IC's burden was to prove by a preponderance of the evidence that Dr. Siems committed the violation alleged in the Complaint in Case 23-13009-1, i.e. that he knowingly or willingly failed to comply with the Board's order confirming his Settlement Agreement.

THE EVIDENCE

The evidence adduced at the April 13 hearing is summarized as follows (bold and italics are inserted by the Hearing Officer):

The IC's Deputy Chief of Investigations and Compliance Officer Johnna LaRue testified that:

Following the Board's approval of the Settlement Agreement entered into between Dr. Siems and the IC, Ms. LaRue mailed notice of the Board's decision to Dr. Siems' then counsel on December 14, 2021. T.15-17;

Ms. LaRue's letter, including a copy of the Settlement Agreement, disclosed the specific requirements with which Dr. Siems would have to comply to meet his obligations under the Settlement Agreement, and the fact that he would have one year from the date of the Board hearing to so comply, which would allow Dr. Siems until December 3, 2022 to meet all the conditions outlined in the Settlement Agreement, and required by the Board's Order thereon. T.18-20;

Receipt of Ms. LaRue's letter containing the Settlement Agreement and Board Order by Dr. Siems' then counsel[1] was confirmed via documentary evidence showing that it was received on December 18, 2021. T.21-22, 26, IC Exhibit 4;

[1] As noted, Dr. Siems was not represented by counsel at the formal Hearing in Case 19-13009-2. However, he retained counsel after the Hearing which culminated in execution of the Settlement Agreement.

Dr. Siems and his counsel both signed the Settlement Agreement. T.28;

Via a November 18, 2022 email to the IC's counsel Mr. White, Dr. Siems' counsel advised Mr. White that he was no longer representing Dr. Siems. T.29-30;

At no time did Dr. Siems' counsel or any other person ever contact Ms. LaRue or anyone else at the Board to request an extension of time for Dr. Siems to complete his requirements under the Settlement Agreement. T.31-33;

Extensions of time to comply with settlement agreement conditions are routinely given under reasonable circumstances. T.33-34;

Dr. Siems did not complete all his CMEs required by the Settlement Agreement within the mandated one-year period, nor did he complete the PACE program. T.34-35. Rather, the last required CMEs were completed within a few days following the February 2, 2023 hearing on the license suspension, (which would have been approximately two months late) . T.35;

Dr. Siems pressed Ms. LaRue on whether the Board should have required him (Dr. Siems) to complete the PACE program when he discovered that the program could not accommodate him. However, Ms. LaRue responded by saying that the Board would have amended the Settlement Agreement had Dr. Siems contacted the Board within the one-year period to advise that PACE could not accommodate him. T.38-43;

In response to Dr. Siems raising the issue of possibly not receiving a copy of the Settlement Agreement from his counsel, Ms. LaRue advised that she had worked a number of times in the past with the same attorney who represented Dr. Siems, and she has never had any issues with practitioners not receiving documents from that attorney. T.45-46;

Had the IC known at any time prior to expiration of his one-year timeline that the PACE program could not presently accommodate Dr. Siems, arrangements would have been made to take the matter back to the Board to alter the terms of the Settlement Agreement. T.47-48;

Dr. Siems recognized a copy of the Settlement Agreement and acknowledged that he signed it. T.51-52;

Dr. Siems acknowledged that he knew his deadline for complying with the terms of the Settlement Agreement was December 3, 2022. T.54;

At some time during December, 2022, Dr. Siems had his manager Isabella call the IC to provide an update on his process of complying with the Settlement Agreement, but not to request an extension of time. T.55-56;

Dr. Siems confirmed that while he does not recall receiving the IC's letter via his counsel following the approval of the Settlement Agreement, that does not mean that he does not remember the "settlement demands." "That's not my claim. I was aware of what the settlement demands were." On questioning by Mr. White, Dr. Siems acknowledged he was aware of the settlement demands as of the date he signed the document, i.e. November 24, 2021. T.57;

Email correspondence between Dr. Siems and the PACE program showed that Dr. Siems was not yet enrolled with PACE as of December 20, 2022, as his outstanding balance due for participation was $10,000.00. The balance due check was dated December 30, 2022, three days after service of the suspension order. T.61, 63-65, Respondent's Exhibits p.0003, 00095;

The first time that Dr. Siems, or his office personnel, contacted the PACE program was October 31, 2022 (or approximately 33 days prior to the compliance deadline in the Settlement Agreement). T.63;

When asked directly if he complied with the terms of the Settlement Agreement, Dr. Siems answered "No." T.65;

Dr. Siems was advised that he had the opportunity to present a defense case, but as the Board and its IC have the burden of proof, he (Dr. Siems) had no obligation to do so. Dr. Siems chose to provide a defense case. T.67-68;

Beginning at page 75 of the transcript, Dr. Siems provided a quite thorough history of some highly traumatic personal crises which began happening in his life in November, 2022, i.e. approximately one month or less before the December 3, 2022 deadline for complying with the Settlement Agreement. Those circumstances include a November 22, 2022 trip to Europe for approximately two weeks due to family medical emergencies,

ongoing emergent care of a young man that Dr. Siems refers to as his step-son upon return to the United States from Europe, and the necessity of a restraining order on December 23, 2022. The undersigned Hearing Officer declines to include details of those matters here to protect the privacy of Dr. Siems' and his family members. Suffice it to say that circumstances involving the mother of his children, and the young man whom Dr. Siems refers to as his step-son, were in crisis stage, which, according to sworn testimony, were physically and emotionally consuming. T.75-141;

Dr. Siems received a letter from the PACE program advising that the program could not accommodate Dr. Siems. That letter was dated April 6, 2023. T.82, Respondent's Exhibits p.0147;

Dr. Siems believes it is the Board's responsibility to determine whether or not the PACE program could accommodate him. Dr. Siems does not feel it is his responsibility to make that determination. T.84;

Dr. Siems testified that he waited four months, i.e. until the PACE program letter of April 6, 2023, to discover / confirm that PACE could not accommodate him. T.89;

Dr. Siems asked his witness Amel Youssef, O.D., if the trauma they jointly experienced because of her son's medical emergencies could distract a person "enough that mundane parts of life, perhaps, were ignored and made oblivious?" She testified in the affirmative. T.114-115;

ANALYSIS

This Hearing Officer did not find any witness who testified at the hearing to have credibility issues. While the witnesses called by Dr. Siems could be argued to be self-serving, those witnesses presented as genuine and factual. This Hearing Officer takes their testimony, along with all of that elicited by the IC, at full face value.

Dr. Siems executed the Settlement Agreement on November 24, 2021. He soon thereafter learned that pursuant to an Order of the Board, he had until December 3, 2022, to complete the conditions of his resolution. He first contacted the PACE program on October 31, 2022, one month and three days before his deadline for full completion of all conditions. That deadline came and went without Dr. Siems handling his CME or PACE

obligations. On December 27, 2022, Dr. Siems' license was summarily suspended for his failure to comply with the conditions of the Settlement Agreement. A formal noticed hearing confirming the suspension was held February 2, 2023. It was after that hearing that Dr. Siems completed his CME requirements, which was more than two months out of compliance. Dr. Siems received a letter confirming that the PACE program could not accommodate him on or after April 6, 2023, just a week prior to the formal Hearing on the Complaint alleging his failure to comply. And while Dr. Siems had his office manager contact the IC with a status update on his compliance at some time in December, 2022, (most likely after his December 3 deadline), at no time – either before or after the deadline - did Dr. Siems or his staff ever request additional time to complete his requirements under the Settlement Agreement.

Dr. Siems offered what is genuinely a compassion-evoking explanation of a series of unfortunate and even tragic events in his life - not the results of his doing - and which no doubt required a great deal of his time and attention. The evidence is clear that he responded well to loved ones in need. His actions were indeed admirable.

Unfortunately, Dr. Siems' defense is measured against three harsh realities. First, as he readily acknowledged, Dr. Siems failed to comply with the terms of his Settlement Agreement and the Board's Order mandating such. Second, Dr. Siems made no contact with the PACE program till he was only thirty-three days away from his deadline. Third, Dr. Siems did not reach out to the IC until after his deadline passed, and even when he had his office manager call, it was to provide a status update and not to seek additional time to comply. Further, it is apparent from the record that the great majority of the challenges that occurred in Dr. Siems' personal life arose either just prior to his compliance deadline – and some even occurred thereafter (such as the necessity of obtaining a restraining order).

Dr. Siems also offers as part of his defense that it should have been the Board's responsibility to ensure that the PACE program could accommodate his area of specialty / expertise before including such in the Settlement Agreement. While not fully articulated in the record, it appears to the Hearing Officer that those involved in crafting the Settlement Agreement had ample cause to believe based on past experience that the PACE program

could serve a physician of Dr. Siems' specialty. It is also apparent from the record that Covid-19 had impacted the ability of the PACE program to accommodate some specialties. Accordingly, the Hearing Officer does not recognize a basis to leave upon the Board sole responsibility for the potential availability of the PACE program to function for Dr. Siems. As stated repeatedly by the IC's counsel Mr. White, had Dr. Siems not waited 333 days to initiate contact with PACE, this case could have been quite different. Ms. LaRue made sufficiently clear that timely notice of any deficiency in the ability of the PACE program to serve in this case would have allowed the Board to amend its requirements. Finally, there is the logical reality that the party on the hook, i.e. the one with his licensure at stake, ought to engage in sufficient due diligence to ensure he is doing all that is required to preserve his valuable practice. Dr. Siems offered no explanation as to why he did not reach out to PACE until October 31, 2022, or why he did not complete his CMEs from the time he signed the Settlement Agreement in November, 2021, until his personal challenges arose in late November 2022. Finally, it must be recognized that Dr. Siems' counsel – who was an extension of Dr. Siems, participated in the negotiating and crafting of the Settlement Agreement. And it was Dr. Siems who executed that Agreement. And accordingly, Dr. Siems shares responsibility for what that Agreement contains.

It is also significant that the statute at issue here is one of strict liability. While Dr. Siems argues that the statute does not prohibit consideration of extenuating circumstances, that does not obviate the plain language of the law that "knowingly or willfully failing to comply with . . . [an] order of the Board constitutes grounds for initiating disciplinary action. The Settlement Agreement became an Order of the Board when the Board approved it. The Order is the final page of the Agreement. Dr. Siems candidly admitted he knew that he did not comply with that Order. The knowing prong of the statute is thus satisfied. And while not a necessary finding or conclusion since either a knowing *or* willful violation will trigger the ramifications of the statute, it can reasonably be determined that Dr. Siems' failure to comply was willful considering the long delay before he took any action whatsoever. The Hearing Officer finds Dr. Siems' passive description of the Board's Order as a "mundane part of life" as a reflection of the amount of concern

he had for the Order, which is further reflected in the long delay before any action was taken whatsoever. In any event, the knowing violation is clear and convincing, thus exceeding the IC's burden of proving their case by a preponderance of the evidence.

CONCLUSION

This Hearing Officer, while readily acknowledging the significant trying life events experienced by Dr. Siems and his family, must recommend that the Board find that Respondent Dr. Jon Lane Siems, M.D., violated the statute as alleged in the Complaint, in that he knowingly failed to comply with the terms of the Order contained within the Settlement Agreement. There is no doubt room for compassion for Dr. Siems in all he experienced in his personal life right around the compliance deadline. But those extenuating circumstances do not negate the knowing failure to meet his mandated obligations, especially when he took no action to inform the Board of those circumstances and/or to seek additional time to comply, or to have the requirements duly amended.

Respectfully submitted this 8th day of May, 2023.



Charles B. Woodman, Hearing Officer

EXHIBIT 2

EXHIBIT 2

NEVADA STATE BOARD OF MEDICAL EXAMINERS
9600 Gateway Drive
Reno, NV 89521

Nick M. Spirtos, M.D., F.A.C.O.G.
Board President

Edward O. Cousineau, J.D.
Executive Director

December 19, 2023

Jon Lane Siems, M.D.
41493 Margarita Road, #G109
Temecula, CA 92591-5570

Re: Compliance Case #23-13009-1

Dear Dr. Siems:

On December 1, 2023, the Nevada State Board of Medical Examiners, approved and accepted the Findings of Fact, Conclusions of Law and Order regarding the complaint filed on Case No. 23-13009-1 finding the following:

- Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3065(2)(a), Knowing or Willful Failure to comply with a Board Order.

As a result, the Board entered its **ORDER** as follows:

- Pursuant to NRS 630.352(4)(e), the Board shall administer a written public reprimand to Respondent;
- Respondent's license shall be suspended for a period of one year, from December 28, 2022 to December 27, 2023. On December 28, 2023, Respondent's license status shall be reinstated to Active-Probation status;
- Respondent shall complete at the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of this Order. Any aforementioned hours of Continuing Medical Education received for attending the program that is substantially related to PACE shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1);
- Respondent shall reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of this Order. The Board, and/or its designee, are granted the authority to collect any and all funds due under this Order;
- Investigation Case Nos. 18-18146, 19-18953, 20-19625, 20-19679, 20-19736, 21-20367, 22-21285, 22-21357, 23-22654, 23-22790, and 23-22844 shall be dismissed with prejudice.

Your compliance with the terms and conditions pertaining to **CME's** will be monitored by Johnna S. LaRue, CMBI, Compliance Officer. Please contact me at (775) 324-9377 for any questions or concerns regarding CME's.

Your compliance with the terms and conditions pertaining to **Administrative Costs and Fines** will be monitored by Donya Jenkins, Chief of Finance and Human Resources. Please contact Ms. Jenkins at (775) 324-9354 for any questions or concerns regarding payment of costs and fines.

Please make note of the Board's new policies for making payments, credit cards, cashier's checks and money orders are the only form of payment accepted.

Payment can be made online at https://nsbme.us.thentiacloud.net/webs/nsbme/service/#/login.

Included in the Order are mandatory actions that you must fulfill some of which include:

1.) The costs in the amount of $7,499.20 are due by **June 1, 2024**.

2.) The University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity is due by **June 1, 2024**.

Please contact me, in writing, **within 30 days** and provide the most expeditious method of contacting you. Thereafter, please update me immediately upon any change in your contact information. You may mail the information to the address below, fax it to 775-688-2553 or e-mail it to me at jlarue@medboard.nv.gov. In addition, any additional information required from you should be submitted to the same contact numbers and address.

If you have any questions, please call, or write. Thank you for your cooperation on this matter.

Respectfully,

Johnna S. LaRue, CMBI
Deputy Chief of Investigations/Compliance Officer
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, NV 89521
(775) 324-9377

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 25, 2024

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:

[redacted]@siemslasik.com

Jon Siems, MD
[redacted]
Las Vegas NV [redacted]

Re: Notice of Suspension of Registration No. CS09874 (Case No. 24-390-CS-S)

Dear Dr. Siems:

The Nevada State Board of Pharmacy (Board) has been notified that your License No. 9250 to practice medicine was summarily suspended by the Nevada State Board of Medical Examiners pursuant to an order entered September 16, 2024. Please be advised that pursuant to NRS 639.2107 this operates as an immediate suspension of your Certificate of Registration No. CS09874 with the Board.

You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

U. S. Department of Justice - Drug Enforcement Administration

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY

File No.

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
JON SIEMS, M.D.	8230 W. SAHARA AVE. STE 111 LAS VEGAS, NV. 89117
DEA REGISTRATION NO. BS4492512	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
NAME AND DATE	TITLE

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.

From: Jon Siems
To: Sanchez, Estevan
Subject: [EXTERNAL] Re: DEA Las Vegas
Date: Monday, November 11, 2024 1:46:17 PM
Attachments: DEA Surrender Form.pdf

Sent from my iPhone

> On Oct 31, 2024, at 3:36 PM, Sanchez, Estevan <Estevan.Sanchez@dea.gov> wrote:
>
> Dr. Siems,
>
> Thank you for speaking with me earlier today.
> Currently, your Nevada medical license is suspended.
> Additionally, your Nevada board of pharmacy registration is suspended.
>
> DEA requires State controlled substance authority. (See below)
> In lieu of a revocation proceeding, you may surrender your DEA#.
> I have attached a form for you to sign and return.
>
> Once you are properly licensed in Nevada – feel free to contact me.
> I will assist with the DEA application process.
>
> Thanks
>
> **
>
> Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[4]
>
> _____
> **Estevan Sánchez** | **DEA Investigator**
> Las Vegas District Office
> Cell: 202-674-4257

Estevan.Sanchez@dea.gov

<DEA Surrender Form.pdf>

5L

FILED
OCT - 4 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ALEXANDER LEE, M.D.,
Certificate of Registration No. CS18089,

Respondent.

Case No. 22-217-CS-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Alexander Lee, M.D. ("Respondent"), because Respondent holds a certificate of registration issued by the Board that authorizes him to prescribe controlled substances in Nevada.

2. The Board has jurisdiction over the subject matter of this accusation because the allegations herein involve the possession, storage, prescribing, and diversion by Respondent of dangerous drugs and controlled substances.

FACTUAL ALLEGATIONS

3. Respondent is a physician licensed by the Nevada Board of Medical Examiners to practice medicine in Nevada. At all times relevant to this accusation, Respondent was a "practitioner" as that term is defined at NRS 639.0125 and NRS 453.126.

4. In 2022, Respondent practiced anesthesiology in the Las Vegas metropolitan area. As an anesthesiologist, Respondent worked at various hospital operating rooms and surgical centers where he anesthetized patients undergoing surgery.

5. The facilities where Respondent practiced anesthesiology in 2022 included the Comprehensive Digestive Surgery Center, located at 8440 W. Warm Springs Road in Las Vegas, Nevada, and the Specialty Surgery Center, located at 7250 Cathedral Rock Drive, in Las Vegas, Nevada. Both facilities are owned and/or operated by HCA Healthcare.

6. Pursuant to NAC 639.4992, the Comprehensive Digestive Surgery Center and the Specialty Surgery Center are both licensed by the Board to operate inpatient pharmacies. These licensed facilities supply all dangerous drugs and controlled substances that are administered by the anesthesiologists and surgeons who perform procedures at the two facilities.

7. Consistent with state and federal law, HCA Healthcare does not allow practitioners to bring their own supplies of dangerous drugs or controlled substances into the procedure rooms where anesthetics are administered to patients before and during surgery.

8. Since November 1, 2020, or earlier, Respondent has held certificate of registration no. CS18089, which was issued by the Board pursuant to NRS 453.226 and NRS 453.231.

9. Respondent's Nevada certificate of registration lists his practice address as 10016 Summit Canyon Drive, Las Vegas, Nevada 89144. Respondent lists no other practice addresses.

10. Since February 21, 2022, or earlier, Respondent has held a controlled substance registration certificate issued by the Drug Enforcement Administration ("DEA") of the U.S. Department of Justice.

11. Respondent's DEA registration certificate lists his practice address as Summerlin Hospital, 657 N. Town Center Drive, Las Vegas, Nevada 89144. Respondent lists no other practice addresses.

12. On July 6, 2022, Respondent anesthetized a patient or patients at the Comprehensive Digestive Surgery Center. On that day, Respondent carried his personal backpack into the procedure room, where he left it unattended. As discussed below, the backpack was later determined to contain a mix of dangerous drugs and controlled substances.

13. On July 6, 2022, staff at the Comprehensive Digestive Surgery Center observed Respondent's personal backpack in the procedure room. Per HCA Healthcare company policy, staff removed the backpack from the procedure room, placed it in an administrative office, and informed Respondent that he was not permitted to bring personal items into the procedure room.

14. On July 6, 2022, staff at the Comprehensive Digestive Surgery Center examined the contents of Respondent's personal backpack and discovered that it contained a mix of dangerous drugs and controlled substances. Staff then took photos of the contents of the backpack. The photos depict a jumble of clear vials inside of a zip lock bag. In the photos, the vials appear to contain a variety of injectable medications.

15. On July 6, 2022, after answering questions about the contents of his personal backpack, Respondent removed his personal backpack and its contents from the administrative office at the Comprehensive Digestive Surgery Center where staff had placed it, and he exited the facility.

16. On July 7, 2022, Respondent anesthetized a patient or patients at the Specialty Surgery Center. On that day, Respondent carried his personal backpack into the procedure room, where he left it unattended. As discussed below, the backpack was later determined to contain a mix of dangerous drugs and controlled substances.

17. On July 7, 2022, staff at the Specialty Surgery Center observed Respondent's personal backpack in the procedure room. Per HCA Healthcare company policy, staff once again removed the backpack from the procedure room, placed it in an administrative office, and reminded Respondent that he was not permitted to bring personal items into the procedure room.

18. On July 7, 2022, staff at the Specialty Surgery Center examined the contents of Respondent's personal backpack and discovered that it contained a mix of dangerous drugs and controlled substances. Some of the drugs and/or controlled substances had expired or were no longer usable due to punctured seals.

19. On July 7, 2022, staff at the Specialty Surgery Center took photographs and prepared a written inventory of the items in the backpack. The inventory revealed that the backpack contained the

following dangerous drugs and controlled substances: Bridion (sugammadex), 6 vials x 200mg/2mL; ketamine, a Schedule III controlled substance, 1 vial x 500mg/10mL; Diprivan (propofol), 1 vial x 200mg/20mL; etomidate, 1 vial x 20mg/10mL; Akovaz (ephedrine sulfate), 50mg/mL; rocuronium, 1 vial x 50mg/5mL; dexamethasone, 10mg/mL; budesonide, 1 vial x 20mg/2mL; hydralazine, 20mg/ml; and albuterol, 90mcg.

20. When questioned about the contents of his personal backpack, Respondent explained that the backpack contained a "stash" of emergency drugs that he carried with him in case the pharmacy at the surgery center did not have what he needed. Respondent indicated that he had taken the drugs from various hospitals and surgery centers in the Las Vegas metropolitan area.

21. During questioning, Respondent emphasized that his stash of dangerous drugs and controlled substances was not for his personal use.

22. Respondent suggested that his practice of removing drugs from certain hospitals and surgery centers, and then administering them in other hospitals and surgery centers, was akin to making "accounting" adjustments. Respondent later clarified, through his attorney, that his conduct was attributable to "an outdated and archaic practice of anesthesiologists—keeping an emergency bag that holds excess medications to ensure patient health/safety in the event a facility lacks needed emergency medication."

23. Respondent has never identified where specifically he obtained the dangerous drugs and controlled substances that were discovered in his personal backpack.

24. In addition to the dangerous drugs and controlled substances described in paragraph 19 above, Respondent's personal backpack contained a vial of clear liquid. The vial had two labels: a manufacturer's label indicating that the vial contained Bridion, and a secondary label indicating that the vial contained fentanyl.

25. When questioned about the conflicting labels described in paragraph 24 above, Respondent stated that he believed the vial contained Bridion, not fentanyl. Respondent suggested that the "fentanyl" label had inadvertently affixed itself to the vial when it was bouncing around in his

backpack. Staff at the Specialty Surgery Center asked Respondent for permission to run a toxicology screen on the contents of the vial. The testing later revealed that the vial contained ethyl alcohol, not Bridion as claimed by Respondent.

26. In addition to the dangerous drugs and controlled substances described in paragraph 19 above, Respondent's personal backpack contained an amber vial of tablets. The label on the amber vial indicated that the tablets were eszopiclone. The label further indicated that the tablets had been prescribed by Respondent for his wife.

27. When questioned about the tablets in the amber vial, Respondent stated that the tablets were metformin, not eszopiclone as indicated on the label. Respondent explained that he had poured his metformin tablets into the amber vial for his own use after his wife had emptied the amber vial. The tablets were later confirmed to be metformin.

28. In addition to practicing anesthesiology, Respondent ostensibly treated patients for endocrine issues and mood and sleep disorders. For example, in 2021 and 2022, Respondent issued six prescriptions for testosterone cypionate, one prescription for clonazepam, one prescription for diazepam, and one prescription for eszopiclone—all controlled substances. The prescriptions were filled by four different pharmacies between October 11, 2021, and May 27, 2022.

29. In 2018, Respondent established an account with the prescription monitoring program ("PMP"). The PMP maintains a database that contains prescription histories for patients who fill their controlled substance prescriptions in Nevada (*see* NRS 453.164). By establishing an account with the PMP, Respondent gained remote access to the PMP database.

30. Respondent did not remotely access or "query" the PMP database until July 13 and 14, 2022, which was well after the above prescriptions were filled (see ¶ 28 above). Respondent queried the PMP database shortly after Board Investigator Dena McClish contacted Respondent concerning the above prescriptions.

31. Respondent later advised Investigator McClish, through his attorney, that he had not previously queried the database because he "experienced technical issues that froze his PMP account

in or around 2018." Respondent further explained, through his attorney, that he was unaware of any legal requirement to query the database in reference to controlled substances other than opiates.

APPLICABLE LAW

32. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing, administering, packaging, labeling or compounding a controlled substance. NRS 453.056.

33. Under Nevada law, any practitioner who dispenses controlled substances in Nevada must obtain a certificate of registration issued by the Board. NRS 453.226. A separate registration is required at each principal place of business or professional practice where the practitioner dispenses controlled substances. NRS 453.226(5).

34. Under federal law, any practitioner who dispenses controlled substances must obtain a certificate of registration issued by the DEA. 21 CFR § 1301.11. A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed. 21 CFR § 1301.12(a).

35. A practitioner may not maintain supplies of controlled substances at any location other than the practitioner's registered place of business or professional practice. NAC 453.130(3)(b); 21 CFR § 1301.12(b)(3).

36. A practitioner must establish and maintain effective controls and procedures to prevent or guard against the theft and misuse of controlled substances. NAC 453.300.

37. A practitioner who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired drugs and unexpired drugs in a storage area from which the substances are withdrawn from inventory for administering or dispensing to patients. NAC 639.050(2); NAC 639.473.

38. A practitioner shall not dispense a controlled substance in violation of a regulation adopted by the Board. NRS 453.381(8).

39. A person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a prescription or order of a practitioner acting in the course of his or her professional practice, or except as otherwise authorized by law. NRS 453.336(1).

40. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge or alteration. NRS 453.331(1)(d).

41. A person shall not possess a dangerous drug unless the drug is furnished to the person by a pharmacist or dispensing practitioner pursuant to a legal prescription, or in the case of possession by a practitioner, unless the drug was lawfully acquired by the practitioner from a manufacturer, wholesaler or pharmacy in stock containers properly labeled. NRS 454.316.

42. It is unlawful for a person to obtain or attempt to obtain possession of a dangerous drug or a prescription for a dangerous drug by misrepresentation, fraud, forgery, deception, subterfuge or alteration. NRS 454.311(1).

43. When a practitioner first obtains a certificate of registration to prescribe controlled substances, the practitioner must enroll in the PMP and complete a course of instruction concerning the use of the PMP database. NRS 453.164(5) and (6); NAC 453.065.

44. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

45. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

46. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions

of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. *See* NRS 639.210(12); NRS 453.231(1)(b); NRS 453.236(1)(e).

47. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4); NRS 453.231(1)(h); NRS 453.236(1)(e).

48. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the person performs his or her duties as the holder of a license issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i) and (j).

49. In lieu of, or in addition to revoking or suspending a practitioner's registration for violating the law or for engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE

Maintaining a Supply of Controlled Substances at an Unregistered Location

50. As alleged above, Respondent transported, in his personal backpack, a supply of controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers. Nevada state and federal law prohibit Respondent from transporting and/or storing controlled substances in this manner.

51. By engaging in the conduct described above, Respondent violated state and federal law relating to controlled substances, specifically NAC 453.130(3)(b) and 21 CFR § 1301.12(b)(3).

52. By engaging in the conduct described above, Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. Accordingly, Respondent is guilty of unprofessional conduct and/or conduct contrary to the public interest. *See* NRS 453.236(1)(e); NRS 639.210(4); NAC 639.945(1)(i).

53. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

COUNT TWO
Failure to Maintain Effective Controls Against Theft or Misuse

54. As alleged above, Respondent transported, in his personal backpack, a supply of controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers. On two or more occasions in 2022, Respondent left his personal backpack unattended at the facilities where he was working.

55. Nevada law imposes upon Respondent a duty to establish and maintain effective controls and procedures to prevent or guard against the theft and misuse of controlled substances. NAC 453.300.

56. By transporting and/or storing controlled substances in the manner described above, Respondent failed to establish and maintain effective controls and procedures to prevent or guard against the theft and misuse of controlled substances.

57. By engaging in the conduct described above, Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. Accordingly, Respondent is guilty of unprofessional conduct and/or conduct contrary to the public interest. *See* NRS 453.236(1)(e); NRS 639.210(4); NAC 639.945(1)(i).

58. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

COUNT THREE
Improper Storage of Dangerous Drugs and/or Controlled Substances

59. As alleged above, Respondent transported, in his personal backpack, a supply of dangerous drugs and controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers. Respondent's supply consisted of a mix of expired and unexpired dangerous drugs and/or controlled substances.

60. By commingling expired and unexpired drugs and/or controlled substances in his personal backpack, Respondent violated NAC 639.050(2) and/or NAC 639.473.

61. Construed together, NAC 639.050(2) and/or NAC 639.473 impose upon practitioners a legal duty to store dangerous drugs and controlled substances in a manner that protects patients from being injected with adulterated substances and/or incorrect drugs.

62. By commingling expired and unexpired drugs and/or controlled substances in his personal backpack, Respondent breached a legal duty to take reasonable precautions to prevent his patients from being injected with adulterated substances and/or incorrect drugs (to include, without limitation, ethyl alcohol mislabeled Bridion and/or fentanyl).

63. By commingling expired and unexpired drugs and/or controlled substances in his personal backpack, Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. Accordingly, Respondent is guilty of unprofessional conduct and/or conduct contrary to the public interest. *See* NRS 453.236(1)(e); NRS 639.210(4); NAC 639.945(1)(i).

64. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

COUNT FOUR
Unlawful Possession of Controlled Substances

65. As alleged above, Respondent knowingly or intentionally acquired controlled substances without a prescription, and from some source other than a manufacturer, wholesaler, or pharmacy. Having acquired controlled substances in this manner, Respondent possessed controlled substances in violation of NRS 453.336.

66. By engaging in the conduct described above, Respondent violated Nevada state law related to controlled substances.

67. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

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COUNT FIVE
Unlawful Possession of Dangerous Drugs

68. As alleged above, Respondent knowingly or intentionally acquired dangerous drugs without a prescription, and from some source other than a manufacturer, wholesaler, or pharmacy. Having acquired dangerous drugs in this manner, Respondent possessed dangerous drugs in violation of NRS 454.316.

69. By engaging in the conduct described above, Respondent violated Nevada state law related to dangerous drugs.

70. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

COUNT SIX
Fraudulent Acquisition of Controlled Substances

71. As alleged above, Respondent knowingly or intentionally removed controlled substances, including ketamine, from the custody of various hospital pharmacies and surgical centers in the Las Vegas metropolitan area. Respondent did so without authority and in a manner intended to avoid detection.

72. Having acquired controlled substances in this manner, namely through the use of deception or subterfuge, Respondent diverted controlled substances in violation of NRS 453.331.

73. By engaging in the conduct described above, Respondent violated Nevada state law related to controlled substances.

74. Having engaged in any one or more of the acts of misconduct described above, Respondent is subject to professional discipline.

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COUNT SEVEN
Fraudulent Acquisition of Dangerous Drugs

75. As alleged above, Respondent knowingly or intentionally removed dangerous drugs from the custody of various hospital pharmacies and surgical centers in the Las Vegas metropolitan area. Respondent did so without authority and in a manner intended to avoid detection.

76. Having acquired dangerous drugs in this manner, namely through the use of deception or subterfuge, Respondent fraudulently possessed dangerous drugs in violation of NRS 454.311.

77. By engaging in the conduct described above, Respondent violated Nevada state law related to dangerous drugs.

78. Having engaged in any one or more the acts of misconduct described above, Respondent is subject to professional discipline

COUNT EIGHT
Failure to Query the PMP

79. As alleged above, in 2021 and 2022, Respondent issued nine prescriptions for controlled substances.

80. Respondent failed to query the PMP to evaluate the prescription histories of the patients for whom he issued the prescriptions.

81. Respondent failed to query the PMP to review prescriptions issued by Respondent and to verify for the Board that he continued to have access to the PMP.

82. By engaging in the conduct described above, Respondent violated NRS 639.23507 and NRS 453.164(7), both of which relate to controlled substances.

83. By failing to query the PMP database as required by Nevada law, Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner, such that he is guilty of unprofessional conduct and/or conduct contrary to the public interest. *See* NRS 453.236(1)(e); NRS 639.210(4); NAC 639.945(1)(i)

84. Having engaged in the conduct described above, Respondent is subject to professional discipline.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Alexander Lee, M.D.

DATED this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALEXANDER LEE, M.D.,** **Certificate of Registration No. CS18089,** **Respondent.**	**Case No. 22-217-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALEXANDER LEE, M.D.,** **Certificate of Registration No. CS18089,** **Respondent.**	**Case No. 22-217-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

ALEXANDER LEE, M.D.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Alexander Lee, MD
[redacted]
Las Vegas, NV [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

HALL&EVANS LLC
ATTORNEYS AT LAW

FILED
DEC 16 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALEXANDER LEE, M.D.,** **Certificate of Registration No. CS18089,** **Respondent.**	**Case No. 22-217-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

I. <u>That Alexander Lee, MD's ("Dr. Lee") Objection To The Notice Of Intended Action And Accusation As Being Incomplete Or Failing To State Clearly The Charges Against Him, Is Hereby Interposed On The Following Grounds</u>:

1. Allegations in Paragraphs 7, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 30, 31, 50-84 as listed in the Notice of Action and Accusation contain a number of misstatements, over-generalizations and inaccuracies.

2. Dr. Lee disagrees with the allegations in Paragraphs 13, 14, 15, 16, 17, 18, 19. On July 6th and 7th, 2022, Dr. Lee brought his personal backpack into two different HCA surgery centers. While doing so, he observed other provider backpacks in the facilities. He acknowledges that his backpack contained some emergency medications, but he did not prepare the written inventory of the items in the backpack and was not involved in the inventory process itself.

3. Dr. Lee disagrees with the allegations in Paragraphs 20, 21, which implies improper possession of dangerous drugs and controlled substances. He does not recall making either of those

1160 North Town Center Drive
Suite 330
Las Vegas, NV 89144
P 702-998-1022
F 303-628-3368
www.hallevans.com

acknowledgments. However, Dr. Lee recognizes that he failed to properly dispose of leftover or unused medications from procedures by safekeeping them in his backpack under the outdated but good-intentioned emergency bag protocol. He further understands that his actions were inconsistent with facility policy and thus, he has re-familiarized himself with the medication disposal policies at all of the facilities that he is credentialed at.

4. Dr. Lee disagrees with the allegations in Paragraphs 24, 25. He was not involved in the testing process for this vial and thus, he has no idea why the testing results indicated the presence of ethyl alcohol.

5. Dr. Lee disagrees with the allegations in Paragraph 22. Dr. Lee recognizes that his actions raised concerns, and he continuously attempted to assure the Board that this matter did not involve diversion of dangerous drugs and controlled substances for personal and/or professional use. Rather, it arises from an outdated and archaic practice of anesthesiologists keeping an emergency bag that holds excess medications to ensure patients' health/safety in the event a facility lacks needed emergency medication. In addition, medications listed in the inventory provided to the Board were never actually used on a patient at any facility and those medications mostly expired while in the bag. The bag itself was not surreptitiously hidden away, it was in plain sight further substantiating the fact that this was not a diversion. Dr. Lee recognizes that while the practice was well-intentioned, it has no place in hospitals and surgery centers today. Further, Dr. Lee immediately ceased bringing any backpack into facilities where he does procedures in response to what occurred on July 6 and 7, 2022.

6. Dr. Lee disagrees with the allegations in Paragraph 23. Dr. Lee did not prepare the inventory of medications allegedly contained in his backpack and was not involved in the inventory process itself, so he has no specific knowledge of staffs' assertions. Dr. Lee previously confirmed that none of the medications found in his backpack were administered to patients. Dr. Lee believes the outdated practice of anesthesiologists carrying an emergency bag was in essence

a security blanket of sorts, providing additional comfort to the anesthesiologist that if a patient suffered an emergency and the facility lacked the needed medications, the patient's life could be saved by the anesthesiologist upon administering the emergency medication. Dr. Lee gave an example of this during his Assessment with the Professional Recovery Network when Dr. Lee explained that in extreme cases of asthma, Ketamine was the go-to drug to open the airway. Dr. Lee further provided another example of how a medication like Ketamine could be used for emergency purposes as during a broncospasm episode at a surgery center if the facility did not have proper anesthesia equipment. Lastly, to the best of his ability, Dr. Lee provided information regarding the legitimate sources of these medications.

7. Dr. Lee disagrees with the allegations in Paragraphs 24, 25. Regarding the vial of Bridion that had a fentanyl label on the vial, upon information and belief, Dr. Lee believes the fentanyl sticker was from an old sticker sheet pad that had come loose from the pad and simply attached to this vial.

8. Dr. Lee disagrees with the allegations in Paragraphs 26, 27. Regarding the bottle of eszopiclone tablets that had Dr. Lee's wife's name on it, that was an old bottle that he used to store his own metformin medication that Dr. Lee has a prescription for. Dr. Lee takes metformin twice a day, but because he frequently forgets to take his morning dosage before leaving for work, he carries that medication with him.

9. Dr. Lee disagrees with the allegations in Paragraphs 28, 29, 30, 31. Regarding PMP, Dr. Lee experienced technical issues that froze his PMP account in or around 2018. He sought assistance from the program's technical support, but became frustrated when that support was not successful in helping him fix the problem. After erroneously believing that the system was only required to check for opiates, and because he does not prescribe opiates, Dr. Lee took no further action on his frozen PMP account. Since, Dr. Lee got his account fixed and received education on the usage and importance of the system.

10. Dr. Lee denies the allegations in Paragraph 30 and 31, particularly the claim that his conduct in relation to the storage or handling of medications constitutes an act of intentional or negligent disregard for professional standards. Dr. Lee asserts that all actions taken were consistent with his professional judgment to prioritize patient safety and ensure the availability of emergency medications, and that there was no willful misconduct or intent to violate any regulations.

11. Dr. Lee denies the allegations in Paragraphs 12-31, including any assertion that his possession or transport of medications was unauthorized or in breach of applicable legal or regulatory frameworks. Respondent maintains that the medications in question were acquired and held solely for the legitimate purpose of providing emergency care, and that there was no intent to misuse or improperly handle these substances.

12. Dr. Lee discussed during his evaluation with the Professional Recovery Network and described the now outdated and archaic practice of anesthesiologists - keeping an emergency bag that holds excess medications to ensure patient health/safety in the event a facility lacks needed emergency medication. Dr. Lee recognizes that while he believed such practice was good-intentioned, it has no place in hospitals and surgery centers today. Further, he immediately ceased bringing any backpack into facilities where he does procedures in response to what occurred on July 6th and 7th, 2022.

II. <u>In Answer To The Notice Of Intended Action And Accusation, Dr. Lee Responds As Follows</u>:

1. Dr. Lee is a board-certified anesthesiologist trained at University of California – San Francisco, University of Washington, and University of California-Davis. He has been licensed in Southern Nevada since 2009 and is the Managing Partner of Zen Anesthesia, a 10-member anesthesia services group located in Las Vegas.

2. Dr. Lee denies allegations in Paragraphs 50-64. Dr. Lee recognizes that his actions raised concerns, and Dr. Lee ongoingly attempted to assure the Board that this matter did not involve diversion of dangerous drugs and controlled substances for personal and/or professional use. Dr. Lee re-familiarized himself with surgery center policies and procedures related to disposing of unused drugs during surgery and other policies such as bringing unauthorized items like a backpack into surgery.

3. Failing to properly dispose of unused medications does not rise to the level of transporting and/or storing controlled substances at unregistered location and/or in improper manner.

4. Failure to dispose of unused and/or expired medications does not involve failure to maintain effective controls against theft or misuse of controlled substances.

5. Dr. Lee denies the allegations in Paragraph 50, specifically that his conduct reflects any unauthorized possession, misuse, or diversion of controlled substances. Dr. Lee asserts that his possession of such substances was solely for patient care purposes and within the scope of his professional responsibilities.

6. Dr. Lee denies the allegations in Paragraph 54, denying any intent to circumvent applicable regulations or act in a manner inconsistent with professional or legal standards regarding the handling of medications.

7. Dr. Lee denies the allegations in Paragraph 55, particularly the assertion that he failed to comply with recordkeeping or inventory requirements for controlled substances. Dr. Lee contends that any perceived discrepancy was unintentional and not reflective of a deliberate violation.

8. Dr. Lee denies the allegations in Paragraph 56, asserting that any handling of medications was done to ensure patient safety and not in a manner that constitutes negligence or misconduct.

9. Dr. Lee denies the allegations in Paragraph 59, specifically the claim that his possession of medications reflects a violation of professional or legal obligations. Dr. Lee asserts that his actions were intended to fulfill his duty to provide optimal patient care.

10. Dr. Lee denies the allegations in Paragraph 60, refuting any assertion of impropriety in his handling of medications and affirming that his conduct was consistent with his professional judgement and responsibilities.

11. Dr. Lee denies the allegations in Paragraph 61, and denies any willful misconduct or intent to act outside the bounds of professional or legal standards.

12. Dr. Lee denies the allegations in Paragraph 62, contending that any perceived irregularities in his actions were unintentional and not indicative of negligence or intentional misconduct.

13. Dr. Lee denies the allegations in Paragraph 63, asserting that his conduct was not reckless or irresponsible but was motivated by the need to ensure patient safety in emergencies.

14. Dr. Lee denies the allegations in Paragraph 64, including any claim that his possession or handling of medications was unauthorized or improper.

15. Dr. Lee denies allegations in Paragraphs 65-78. Dr. Lee did not possess culpable mental state to be liable as asserted in allegations in Paragraphs 65-78. These are serious allegations and require a joint operation of act and intention. As previously explained by Dr. Lee and as supported by Mark Chase, Clinical Program Director at the Professional Recovery Network and MEC committees of various medical facilities, Dr. Lee did not possess intent to be found liable. Having medications in his backpack arises from an outdated and archaic practice of anesthesiologists - keeping an emergency bag that holds excess medications to ensure patient health/safety in the event a facility lacks needed emergency medication. Dr. Lee did not acquire any controlled substances through deception or subterfuge as asserted in the Notice of Action and Accusation, but rather he failed to properly dispose of leftover or unused medications from

procedures by safekeeping them in his backpack under the outdated but good intentioned emergency bag protocol. He recognizes that while this practice was good-intentioned, it has no place in hospitals and surgery centers and has ceased this practice.

16. Dr. Lee denies the allegations in Paragraph 65, specifically denying that his conduct constitutes a breach of any specific laws or regulations cited in this paragraph.

17. Dr. Lee denies the allegations in Paragraph 66, asserting that any actions taken with respect to medications were within the scope of his professional judgement and intended solely to benefit patients.

18. Dr. Lee denies the allegations in Paragraph 67, refuting any claim that his actions were inconsistent with legal requirements.

19. Dr. Lee denies the allegations in Paragraph 68, particularly the assertion that his actions were willfully or negligently inconsistent with the standards governing the safe handling, storage, or use of controlled substances and dangerous drugs. Dr. Lee maintains that all medications were stored and utilized in a manner that prioritized patient safety and compliance with applicable laws to the best of Dr. Lee's understanding.

20. Dr. Lee did not prepare the inventory of medications that are listed in the Notice of Action and Accusation, and that were provided to the Board by the facility's staff. Dr. Lee was not involved in the detailed inventory process itself, but he acknowledges that his backpack contained emergency medications. In Dr. Lee's experience, certain emergency medications are not readily available in various surgery centers, the ER or the ICU: etomidate for sedation, Bridion for neuromuscular reversal, and ketamine for asthma exacerbation or sedation.

21. Dr. Lee denies the allegations in Paragraph 71, which suggest that his possession of medications was unauthorized or in violation of regulations. Dr. Lee asserts that all medications in his possession were retained for legitimate medical purposes, specifically to address emergencies and potential shortages in facilities where he provided care.

22. Dr. Lee denies the allegations in Paragraph 75 that his conduct constitutes a violation of any specific provision of law cited therein. Dr. Lee asserts that his practices, while potentially reflective of outdated methodologies, were motivated solely by the need to ensure uninterrupted patient care and were not intended to circumvent legal or regulatory requirements.

23. In addition, the medications allegedly contained in Dr. Lee's backpack were never used on a patient at any facility and as the inventory of medications describes and Notice of Action and Accusation states, those medications mostly expired while in the backpack.

24. Dr. Lee denies the allegations in Paragraph 76, which imply that his actions demonstrated a disregard for regulatory oversight or patient safety. Dr. Lee reiterates his commitment to upholding professional standards and emphasizes that any deviations were unintentional and occurred in the context of ensuring readiness to address patient needs.

25. The bag itself was not surreptitiously hidden away, it was in plain sight further substantiating the fact that this was not diversion, deception or subterfuge.

26. Dr. Lee underwent a professional evaluation in July of 2022, as directed by Southern Hills Hospital. The Evaluation from Mark Chase, Clinical Program Director at the Professional Recovery Network states that Dr. Lee is safe to practice as a medical doctor and be able to exercise his facility privileges without restriction.

27. The evaluator also acknowledges the now outdated protocol of anesthesiologists maintaining an emergency bag of medications and opines that he does not believe that Dr. Lee was stealing leftover or unused drugs. Therefore, allegations in Paragraphs 68-78 are not supported by any admissible evidence but rather refuted by a licensed medical evaluator, Mark Chase.

28. The recommendations in the Evaluation include having Dr. Lee re-familiarize himself with hospital and surgery center policies and procedures related to disposing of unused drugs during surgery and other policies such as bringing unauthorized items like a backpack into surgery.

29. Dr. Lee has completed both of these recommendations and will continue to remain aware about such matters.

30. Importantly, after hearing from Dr. Lee and reviewing the Evaluation, the HCA facilities have taken the following actions:

- Specialty Surgery Center - on August 4, 2022, the MEC lifted the precautionary suspension. No disciplinary or corrective action was imposed.
- Comprehensive Digestive Surgery Center - on August 4, 2022, the MEC lifted the precautionary suspension. No disciplinary or corrective action was imposed.
- Southern Hills Hospital - on August 5, 2022, Dr. Lee was notified that the MEC had terminated his refrain agreement and that he could resume exercising his privileges. No disciplinary or corrective action was imposed.
- Mountain View Hospital – the facility terminated Dr. Lee's refrain agreements and allowed him to resume exercising his privileges. No disciplinary or corrective action was imposed.
- Sunrise Hospital - the facility terminated Dr. Lee's refrain agreements and allowed him to resume exercising his privileges. No disciplinary or corrective action was imposed.
- This further contravenes allegations in Paragraphs 68-78. At no time did Dr. Lee divert medications for unlawful purposes or personal benefit.

31. Dr. Lee denies the allegations in Paragraphs 79-84. As it pertains to PMP allegations, Dr. Lee experienced technical issues that froze his PMP account in or around 2018.

He sought assistance from the program's technical support, but became frustrated when that support was not successful in helping him fix the problem. After erroneously believing that the system was only required to check for opiates, and because he does not prescribe opiates, Dr. Lee took no further action on his frozen PMP account. Dr. Lee got his account fixed and received education on the usage and importance of the system.

32. Any perceived failures to comply with standards for the storage, handling, documentation of medications or PMP access was unintentional and not reflective of willful or negligent misconduct. Dr. Lee has consistently acted in good faith with the intention of safeguarding patient health. Dr. Lee has made efforts to adhere to all applicable laws and regulations to the best of his understanding. If any deficiencies were identified, they are attributable to misunderstanding or misinterpretation rather than intentional disregard for rules and regulations.

33. Nothing herein is or shall be deemed to be a waiver or release of any rights, remedies, or defenses.

34. Dr. Lee reserves the right to present evidence and testimony to clarify and refute the allegations, contained in the Notice of Action and Accusation.

35. Denials as contained in Dr. Lee's Answer and Notice of Defense are made without prejudice to assert additional defenses that may be raised after further review of the allegations and evidence.

36. Dr. Lee reserves the right to provide further evidence and testimony to support these denials and clarify any misunderstandings or inaccuracies in the allegations.

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Wherefore, Dr. Lee respectfully requests that the Nevada State Board of Pharmacy dismiss the allegations and grant such further relief as deemed just and appropriate.

DATED this 16th day of December 2024.

HALL & EVANS LLC

/s/ Adam Knecht
Adam R. Knecht, Esq.
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JESSE BRADBERRY, PTT,** **Certificate Registration No. PT28790,** **Respondent.**	**Case No. 23-490-PTT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Jesse Bradberry (Respondent), because Respondent, at the time of the violations alleged herein, held a Certificate of Registration issued by the Board pursuant to NRS 639.100 and NRS 639.1371, authorizing Respondent to work as a pharmaceutical technician in training. Since June 13, 2023, Respondent has held Certificate of Registration No. PT28790, allowing him to work as a pharmaceutical technician in training issued by the Board pursuant to NRS 639.100 and NRS 639.1371.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the issuance of Certificates of Registration as required by Nevada law and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent submitted a pharmaceutical technician in training (PTT) application on or around June 13, 2023.

4. Respondent did not disclose any arrests, charges, or convictions in any state on his PTT application.

5. On or around September 20, 2023, Respondent submitted a pharmaceutical technician (PT) application to the Board.

6. Respondent later admitted that he failed to disclose arrests and/or convictions on his original PTT application submitted on June 13, 2023.

7. The Board issued a Citation-and-Fine Letter to Respondent dated December 28, 2023.

8. Respondent was issued an administrative fine of $500.00 for failing to properly disclose previous arrests, charges, and/or convictions on his original PTT application.

9. Respondent failed to timely pay the fine or submit a written request for appeal within the statutory 30-day timeframe to do so. NRS 639.2895(2).

10. Respondent's fine was sent to collections pursuant to Nevada law. NRS 353C.195(3).

11. Respondent continues to hold a PTT registration despite not having complied the Board's Citation-and-Fine Letter.

APPLICABLE LAW

12. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

13. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

14. The Board has the authority to register PTTs pursuant to NAC 639.242.

15. The Board may issue a Citation-and-Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

16. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

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COUNT ONE

Unprofessional Conduct – Failure to Comply with a Board Citation-and-Fine Order

17. Respondent failed to comply with a Board Citation-and-Fine Order in a timely manner. NRS 639.2895(2). The Citation-and-Fine Order was lawfully issued pursuant to NRS 639.2895 and NRS 639.100(1)(b). Respondent was required to either pay the $500.00 fine or submit a written appeal request within 30 days of the issuance of the letter. NRS 639.2895(2). Respondent failed to do either.

18. Because of these actions, Respondent performed his duties as the holder of a registration issued by the Board in an incompetent, unskillful or negligent manner. Respondent performed his duties in an incompetent, unskillful, or negligent manner because he failed to comply with a Board Citation-and-Fine Order. NRS 639.210(4); NAC 639.945(1)(i).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JESSE BRADBERRY, PTT,** **Certificate of Registration No. PT28790,** **Respondent.**	**Case No. 23-490-PTT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JESSE BRADBERRY, PTT,** **Certificate of Registration No. PT28790,** **Respondent.**	**Case No. 23-490-PTT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JESSE BRADBERRY, PTT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jesse Bradberry, PTT
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STUART BERLINER, RPH,** **Certificate of Registration No. 12908,** **Respondent.**	**Case No. 24-161-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Stuart Berliner, RPh (Respondent), because Respondent, at the time of the violations alleged herein, held a Certificate of Registration issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to work as a pharmacist. Since April 5, 1996, Respondent has held Certificate of Registration No. 12908, allowing him to work as a pharmacist issued by the Board pursuant to NRS 639.100 and NRS 639.127.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the issuance of Certificates of Registration as required by Nevada law and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent held a license allowing him to work in the State of Nevada as a pharmacist during the biannual renewal period from November 1, 2021, to October 31, 2023.

4. Respondent's renewal application for the 2021-2023 biannual renewal period lists that he resided at an address in Las Vegas, NV. This address is the last known address for this licensee that the Board has.

5. Respondent failed to submit the 30 required continuing education (CE) hours required by Nevada law by the October 31, 2023, deadline.

6. Respondent was issued a Citation-and-Fine Order by the Board for not completing his CE hours in a timely manner. The Citation-and-Fine Order required Respondent to pay an administrative fine of $500.00 and to submit the required CE hours by July 31, 2024, or to appeal the Order by submitting a written request for appeal to the Board within 30 days.

7. Respondent failed to pay the administrative fine and submit the required 30 CE hours by the July 31, 2024, deadline.

8. Respondent also failed to submit a request for an appeal of the Order within the statutorily prescribed 30 days. NRS 639.2895(2).

9. Respondent continues to hold a pharmacist certificate of registration with the Board despite not having completed the requirements prescribed by Nevada law to keep the registration.

10. Respondent has also failed to comply with the Citation-and-Fine Order issued by the Board on May 22, 2024.

APPLICABLE LAW

11. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

12. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

13. The Board may issue a Citation-and-Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

14. "The Board shall adopt regulations necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued

and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the Board may determine to be necessary." NRS 639.2176.

15. "The Board will not issue a certificate as a registered pharmacist to any person pursuant to NRS 639.127, or renew the certificate of any registered pharmacist, until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period." NAC 639.330(1).

16. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Comply with a Board Citation-and-Fine Order

17. Respondent failed to comply with a Board Citation-and-Fine Order in a timely manner. NRS 639.2895(2). The Citation-and-Fine Order was lawfully issued pursuant to NRS 639.2895 and NRS 639.100(1)(b). NRS 639.2176; NAC 639.330(1). Respondent was required to either pay the $500.00 fine and submit the required CE hours or submit a written appeal request within 30 days of the issuance of the letter. NRS 639.2895(2). Respondent failed to do either.

18. Because of these actions, Respondent performed his duties as the holder of a registration issued by the Board in an incompetent, unskillful or negligent manner. Respondent performed his duties in an incompetent, unskillful, or negligent manner because he failed to comply with a Board Citation-and-Fine Order. NRS 639.210(4); NAC 639.945(1)(i).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

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WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STUART BERLINER, RPH,** **Certificate of Registration No. 12908,** **Respondent.**	**Case No. 24-161-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STUART BERLINER, RPH,** **Certificate of Registration No. 12908,** **Respondent.**	**Case No. 24-161-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

STUART BERLINER, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Stuart Berliner, RPH
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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FILED
OCT 07 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEDICAL N MOBILITY,** **License No. MP00250,** **Respondent.**	**CASE NO. 24-219-MP-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Medical N Mobility ("Respondent"), held Nevada Medical Products Provider License No. MP00250, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about May 21, 2024, the Board conducted an inspection of Respondent's facility located at 7270 West Lake Mead Blvd., #190, Las Vegas, NV 89128, and discovered that Respondent was operating without an approved administrator for its medical products provider facility.

3. Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

4. Respondent continued its Medical Products Provider operations for more than ten (10) business days without an approved facility administrator.

5. Respondent admitted in a letter to the Board that the current administrator was not approved by the Board and that they were working to fix the issue.

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APPLICABLE LAW

6. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

7. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit. NRS 639.210(12).

8. Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must be approved by the Board. NAC 639.694(1)(e).

9. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment. NAC 639.694(3).

10. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator. NAC 639.694(4).

11. A medical products wholesaler shall employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler. NAC 639.6957(1)(a).

12. Any violation of these regulations or violation of any applicable federal, state or local laws related to the practices of the medical products provider or medical products wholesaler is unprofessional conduct. NAC 639.6941(1)(a).

13. It is unprofessional conduct to perform any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

14. The Board may, in addition to suspending or revoking a license, impose a fine of not more than $10,000.00 on a Respondent per offense. NRS 639.255(3).

COUNT ONE

Failure to Employ Facility Administrator – Violation of State Law(s)

14. Respondent failed to comply with NAC 639.694(1)(e); NAC 639.694(3) and (4); as well as NAC 639.6957(1)(a) when it neglected to timely notify the Board of the departure of its facility administrator and continued its operations as a Medical Products Provider without timely obtaining approval of a qualified facility administrator; therefore, Respondent is subject to discipline pursuant to NRS 639.210(12) and NRS 639.255.

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By violating NAC 639.694(3) and (4) and NAC 639.6957(1)(a), as detailed above, Respondent engaged in unprofessional conduct and conduct contrary to the public interest, as set forth in NAC 639.6941(1)(a), and performed its duties as the holder of a Medical Products Provider license in an incompetent, unskillful, or negligent manner in violation of NAC 639.945(1)(i); therefore, Respondent subject to discipline pursuant NRS 639.210(4) and NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 7th day of October 2024.

J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEDICAL N MOBILITY,** **License No. MP00250,** **Respondent.**	**Case No. 24-219-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEDICAL N MOBILITY,** **License No. MP00250,** **Respondent.**	**Case No. 24-219-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR MEDICAL N MOBILITY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Medical N Mobility
7270 W Lake Mead #190
Las Vegas, NV 89128

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

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FILED
SEP 11 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**CASE NO. 24-281-MP-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Orthopedic Motion, Inc. ("Respondent"), held a Nevada Medical Products Provider License No. MP00772, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about July 2, 2024, the Board conducted an inspection of Respondent's facility located at 3233 W. Charleston Blvd., Las Vegas, NV 89102, and discovered that Respondent was operating without an approved administrator for its Medical Products Wholesaler facility.

3. Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

4. Respondent continued its Medical Products Provider operations for more than ten (10) business days without an approved facility administrator.

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APPLICABLE LAW

5. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

6. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit. NRS 639.210(12).

7. Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must be approved by the Board. NAC 639.694(1)(e).

8. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment. NAC 639.694(3).

9. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator. NAC 639.694(4).

10. A medical products wholesaler shall employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler. NAC 639.6957(1)(a).

11. Any violation of these regulations or violation of any applicable federal, state or local laws related to the practices of the medical products provider or medical products wholesaler is unprofessional conduct. NAC 639.6941(1)(a).

12. It is unprofessional conduct to perform any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

FIRST CAUSE OF ACTION

Failure to Employ Facility Administrator – Violation of State Law(s)

13. Respondent failed to comply with NAC 639.694(1)(e); NAC 639.694(3) and (4); as well as NAC 639.6957(1)(a) when it neglected to timely notify the Board of the departure of its facility administrator and continued its operations as a Medical Products Provider without timely obtaining approval of a qualified facility administrator; therefore, Respondent is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. By violating NAC 639.694(3) and (4) and NAC 639.6957(1)(a), as detailed above, Respondent engaged in unprofessional conduct and conduct contrary to the public interest, as set forth in NAC 639.6941(1)(a), and performed its duties as the holder of a Medical Products Provider license in an incompetent, unskillful, or negligent manner in violation of NAC 639.945(1)(i); therefore, Respondent subject to discipline pursuant NRS 639.210(4).

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WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of September 2024.

J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**Case No. 24-281-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 16, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of September 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**Case No. 24-281-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR ORTHOPEDIC MOTION, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of Sept. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Orthopedic Motion, Inc.
3233 W Charleston Blvd. #111
Las Vegas, NV 89102

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

September 11, 2024

VIA CERTIFIED U.S. MAIL & ELECTRONIC MAIL

Obiechina Ezekwesili, Pharm.D. (Unlicensed)
Echo Health LLC, dba Nova Specialty Pharmacy
2651 E. Broad Street, Suite 101
Mansfield, TX 76063
Email: pharmacy@novaspecialtypharmacy.com

CEASE-AND-DESIST and CITATION-AND-FINE: Case No. 24-354-PH-O – Unlicensed Operation of a Pharmacy and Practice of Pharmacy in Nevada

To Whom it May Concern:

The Nevada State Board of Pharmacy (hereinafter "Board") has determined that you own and serve as the managing pharmacist of Echo Health LLC, dba Nova Specialty Pharmacy (hereinafter "Nova"). The Board has also found that Nova is operating an unlicensed pharmacy in the state of Nevada. Nova sold or dispensed prescriptions to Nevada-based patients at least 103 times. Additionally, according to an inspection report obtained from the Texas State Board of Pharmacy, Nova failed to maintain quality standards for the compounded drugs that it dispensed to its Nevada-based patients. Failure to adhere to proper quality standards when compounding drugs may result in patient harm.

Under Nevada law, no person (including a pharmacy or pharmacist) may manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded, any prescription of a practitioner, unless the person holds the appropriate license and complies with the regulations adopted by the Board. NRS 639.100(1). Any person who violates NRS 639.100(1) may be charged with a felony. *See* NRS 639.100(2). Additionally, any person engaged in the unlicensed practice of pharmacy in Nevada may be subject to administrative fines and/or claims for injunctive relief. NRS 639.2895. By shipping prescriptions into the state of Nevada at least 103 times, Nova has sold or dispensed a drug without the appropriate license (a pharmacy license) at least 103 times. Further, as Nova's owner and managing pharmacist, you caused or permitted Nova to sell or dispense drugs on each of these occasions, thereby engaging in the unlicensed practice of pharmacy.

In addition to being properly licensed, a pharmacy and/or pharmacist must comply with all applicable regulations adopted by the Board. Based on the Texas report noted above, Nova failed to comply with compounding regulations adopted by the Board at least 28 times. *See* NRS

9171 9690 0935 0313 5396 45

639.210(4); NRS 639.210(15); NAC 639.482; NAC 639.485; NAC 639.670; NAC 639.6705; NAC 639.67037; NAC 639.67069; NAC 639.67077; NAC 639.67079; NAC 639.6701; NAC 639.67013; NAC 639.67019; NAC 639.6702; NAC 639.67055; NAC 639.707; NAC 639.708; NAC 639.751; NAC 639.945(1)(a); NAC 639.945(1)(f); NAC 639.945(1)(j); and NAC 639.945(1)(k). Please note that some of the regulations listed previously have been purportedly violated in multiple ways and/or more than once. Finally, the Board also has evidence that Nova failed to employ a Nevada licensed pharmacist during the period of time they shipped drugs into Nevada, in violation of Nevada law. NRS 639.2328.

As noted previously, the Board may seek injunctive relief and/or impose administrative fines against any person engaged in the unlicensed practice of pharmacy in Nevada. In this case, you and/or your employer, Echo Health LLC, dba Nova Specialty Pharmacy, are jointly and severally liable for a fine of up to $5,000 for each of the 131 violations identified above. NRS 639.100(3). NRS 639.2895.

Accordingly, the Board hereby orders you to immediately **CEASE and DESIST** your operation of an unlicensed pharmacy in the state of Nevada. Do not ship any more drugs or fill any more prescriptions for Nevada-based patients. Additionally, this letter shall serve as a **CITATION** pursuant to NRS 639.2895(2) for operating a pharmacy and engaging in the practice of pharmacy in this state without having obtained the required pharmacy license and/or pharmacist registration issued by the Board. Based on the above evidentiary summary, the Board has assessed **administrative fines** against you and/or your employer in the total amount of **Six Hundred and Fifty-Five Thousand Dollars and 00/100 Cents ($655,000.00).**

If you do not intend to contest the above fines, please pay the amount listed above within 30 days of receipt of this citation, or otherwise contact Board staff to request an extension for good cause shown. Payment must be made by *certified check, cashier's check,* or *money order* payable to **"State of Nevada, Office of the Treasurer,"** and it must be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You may appeal this citation by submitting a notice of appeal requesting a public hearing before the Board. You must submit any such notice of appeal not later than 30 days after receipt of this citation. NRS 639.2895(2). Please mail or personally deliver any notice of appeal to the Reno address listed on the letterhead.

Pursuant to the Nevada Public Records Act, this citation constitutes a public record that must be released to anyone who makes a proper request for it. Additionally, once it becomes a final determination in accordance with the Nevada Administrative Procedure Act, this matter will be reported to the National Practitioner Data Bank. If you have any questions, please contact the Board's General Counsel, Gustaf Vanderdonck, at 775-850-1440, ext. 132, or *via* email at gvanderdonck@pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy

NOVA

FILED
SEP 11 2024
NEVADA STATE BOARD
OF PHARMACY

To Whom It May Concern:

You've probably heard the quote, an entrepreneur leaps first, "then builds the plane on the way down." Well here I am, and this is the story about my leap of faith.

My name is Obiechina N. Ezekwesili, Founder and director of pharmacy at Nova Specialty Pharmacy. I am currently in violation of compliance and write to you to seek reconciliation. It was never my intention to violate any board rules. When I first birth this idea, the dream was to build a pharmacy solutions company, similar to TruePill, for sterile compounding. In my pursuit, an opportunity presented itself to partner with several brands to dispense vitamins and GLP1s, amongst other products. Adhering to the strictest guidelines, policies and procedures, and focusing solely on patient satisfaction and positive outcomes, I leaped.

My journey to pharmacy began on August 19, 1996, in Enugu, Nigeria, the day my father died. My father was poisoned by an evil man, and the antidote to save his life was not in stock due to the poor conditions and lack of funding for the state hospital where he died at. My dream was to grow up and launch a global pharmaceutical non-profit, that would bridge the gap between the desolate and resources they need to survive, making preventable deaths, preventable again. In pursuit of that vision, I launched my first pharmacy during my third year of pharmacy school, Velox Pharmacy Solutions, a discount pharmacy offering prescriptions at the wholesale cost, plus an ethical mark up of $7, similar to what Mark Cuban is doing with his.(https://www.wsaz.com/content/news/Couple-opens-new-pharmacy-to-help-people-afford-medications-565358922.html) I did this by winning several business plan competition in the state of West Virginia, as well as nationally. I highlight his story to show the sincerity of my heart. I am not one of the many that seek this GLP1 goldrush for the monetary value, but rather, I pursue it to provide access to affordable care, as I have always pursued.

I beseech you to have mercy. This plane that I've built, has flown into unauthorized airspace, please don't shoot me down. I was under the impression that becoming 503B would be the solution to allow us to ship nationwide, but that has been proven vague as well. It is my hope that the board will work with my company, to educate us, and allow us an opportunity to become compliant, and continue to serve the people of your state.

I look forward to hearing from you.

At your mercy,

Dr. Obiechina N. Ezekwesili

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FILED
SEP 0 4 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-N** **23-063-RPH-N** **STIPULATION AND ORDER** **[American Wellness Pharmacy ONLY]**

J. David Wuest, in his capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, by and through counsel, Trevor R. Waite, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 18, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about July 19, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. American Wellness Pharmacy compounded and sold drug products using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto;

B. American Wellness Pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD;

C. American Wellness Pharmacy's personnel violated NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a;

D. As the pharmacy/pharmacy owner at which the violations alleged herein occurred, American Wellness Pharmacy is responsible for those violations, including all errors and omissions of the pharmacy personnel, and subject to discipline pursuant to pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3); and

E. Personnel of American Wellness Pharmacy engaged in unprofessional conduct as defined in NAC 639.945(1)((i), and American Wellness Pharmacy is therefore subject to discipline pursuant to NAC 639.945(3) and 639.210(4).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The pharmacy license of American Wellness Pharmacy, Pharmacy License No. PH02705, is suspended for a period of one (1) year pursuant to NRS 639.255(1)(c). The suspension is stayed, and Respondent is placed on probation subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Eight Thousand Dollars ($8,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024;

B. Pursuant to NRS 622.400, Respondent shall pay Two Thousand Dollars ($2,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024;

C. Respondent shall not compound sterile drug products during the probation period;

D. Board inspectors shall conduct quarterly inspections of American Wellness Pharmacy for the probation period, and Respondent shall bear and reimburse the Board for inspection costs in an amount not to exceed $500 per quarterly inspection;

E. Respondent shall establish and put into practice all necessary policies and procedures for compounding and dispensing drug products in conformance with federal and state law; and

F. Respondent shall have no new charges filed against American Wellness Pharmacy while on probation.

Upon successful completion of probation, Respondent's License No. PH02705 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay of suspension and immediately suspend Respondent's License No. PH02705 and may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 26 **day of** August **2024**

Eytan Klepach
AMERICAN WELLNESS PHARMACY,
Pharmacy License No. PH02705

Signed this 3RD **day of** SEPTEMBER **2024**

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 26 **day of** August **2024**

Trevor Waite
TREVOR R. WAITE, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, in Case No. 23-063-PH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this 4th day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

American Wellness Pharmacy
2755 S. Jones Blvd., Suite 100A
Las Vegas, NV 89146

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

FILED
OCT 16 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-S** **23-063-RPH-S** **ORDER GRANTING APPLICATION FOR RECONSIDERATION AND AMENDING STIPULATION AND ORDER** **[American Wellness Pharmacy ONLY]**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, September 4, 2024, in Las Vegas, Nevada. Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, appeared by and through counsel, Trevor Waite. The parties presented a stipulation to the Board for discussion and approval pursuant to NRS 622.330(1), The stipulation was unanimously approved by the Board, filed and entered as the final decision in Case No. 23-063-PH-S on September 4, 2024 (hereinafter 'Stipulation and Order' – Exhibit A hereto).

On or about September 21, 2024, Respondent, by and through counsel, Kimberly Maxson-Rushton, Esq., filed an Application for Rehearing or Reconsideration of Paragraph 8(C) of the Stipulation and Order pursuant to NRS 622A.390(1) and NRS 639.252. Respondent and counsel appeared before the Board on October 16, 2024, to answer questions and give testimony and evidence regarding the Application.

Respondent's Application is GRANTED pursuant to NRS 622A.390 and NRS 639.252. Paragraph 8(C) of the Stipulation and Order is amended by removing the requirement that Respondent shall not compound sterile drug products during the probation period, and replacing that prohibition with the following:

Paragraph 8(C): Prior to resuming the compounding of sterile drug products, Respondent shall comply with the following requirements:

(i) Respondent shall generate and provide to Board staff a list identifying by name, address, telephone number, and prescription number all patients that were dispensed compounded drug products that were mislabeled with inaccurate beyond use dates in the two (2) years prior to the date of this Order. All patients identified shall be provided written notification that the drug product was dispended with a beyond use date listed that was fifteen times the period permitted. The notice shall also state that the patient may request a refund of the amount the patient paid for the mislabeled drug product. The notification form shall be subject to prior approval by Board staff.

(ii) Consistent with NAC 639.67013, the managing pharmacist and a designated person (technician) shall complete the USP Implementation Training, CORE Compounding Training and Sterility Assurance Training courses through accredited vendor PCCA; training will take place onsite and online at https://www.pccarx.com/PCCAEducation/Pharmacy. Documentation of successful completion shall be provided to Board staff.

(iii) Consistent with NAC 639.67013, the managing pharmacist and a designated person (technician) shall complete all modules comprising the Sterile Compounding Training Schedule through Critical Point at https://www.criticalpoint-lms.com. Documentation of successful completion shall be provided to Board staff.

(iv) Upon completion of items (i)-iii), Respondent shall be subject to inspection by Board staff pursuant to NRS 639.090 and NRS 639.289.

Upon resuming the compounding of sterile drug products, Respondent shall comply with the following requirements:

(v) Consistent with NAC 639.67013, each pharmacist and pharmaceutical technician shall complete the training specified in items (ii) and (iii) prior to engaging in the practice of compounding sterile drug products.

(vi) Respondent shall undergo at least two (2) inspections by the National Association of Boards of Pharmacy (NABP) during the probation period, with all findings provided directly to Board staff.

This Order is effective immediately.

IT IS SO ORDERED.

Entered this 16th day of October 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Kimberly Maxson-Rushton, Esq.
Cooper Levenson, Attorneys at Law
3016 W. Charleston Blvd., Suite 195
Las Vegas, NV 89102

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

COOPER LEVENSON
ATTORNEYS AT LAW

3016 W. Charleston Blvd., Suite 195
Las Vegas, NV 89102
Phone (702) 366-1125
Toll Free (800) 529-3161
Fax (702) 366-1857
www.cooperlevenson.com

Direct Phone: (702) 832-1900
Direct Fax: (702) 832-1901

KIMBERLY MAXSON-RUSHTON
EMAIL: krushton@cooperlevenson.com

FILE NO.

December 24, 2024

Via E-mail

David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

Re: Stipulation and Order Request

Dear Mr. Wuest:

Please allow this to serve as a request on behalf of American Wellness Pharmacy ("American Wellness") to have the October 16, 2024 Stipulation and Order added to the Board's January agenda for clarification. Specifically, my clients seek clarification of the terms mutually agreed to by the parties and whether said terms have been met.

As always, thank you for your consideration of this request.

Sincerely,

Kimberly Maxson-Rushton

cc: George Maiorano
Eytan Klepach

4901-6910-1833, v. 1

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04491		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Advance Pharma

Physical Address: 5000 W Oakey Blvd Suite B7

City: Las Vegas State: Nevada Zip: 89146

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-3419316 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-4632668 Contact Email: info@advancepharma.us

Website: www.advancepharma.us

Nevada Business License # (if applicable) NV20222583742

Supervising/Managing Pharmacist Name (NRS 639.220): Richard D. Nguyen

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20757

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Richard D. Nguyen	NV Pharmacist Registration #: 20757
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): _____

Corporation/Organization Name: ADVANCE PHARMA

Mailing Address: 5000 W Oakey Blvd Suite B7

City: Las Vegas State: Nevada Zip: 89146

Telephone: 702-3419316 Email: info@advancepharma.us

Contact Person Name: Vladimir Hernandez

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

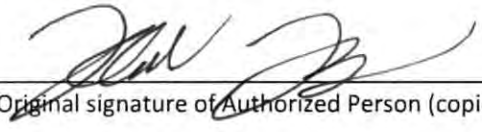
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Advance Pharma (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Richard D. Nguyen

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

03/25/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Richard D. Nguyen hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST (title) for ADVANCE PHARMA (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of March, 2024

Notary Public

NOTARY PUBLIC
STATE OF NEVADA
County of Clark
VLADIMIR HERNANDEZ
Appt. No. 16-4403-1
My Appl. Expires Dec. 4, 2024

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Richard D. Nguyen Pharmacist Registration #: 20757

Pharmacy Name: ADVANCE PHARMA

Initial each statement below to indicate you have read and agree with the following:

RN I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

RN I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

RN I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

RN I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

RN I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

03/25/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VLADIMIR HERNANDEZ

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

03/25/2024

Date

Board Use Only	Date Received: 3/28/24	Amount: $500-CC

NEVADA STATE BUSINESS LICENSE

ADVANCE PHARMA

Nevada Business Identification # NV20222583742
Expiration Date: 09/30/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/21/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202408214895602
You may verify this certificate online at

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE President:				
Yailen Matos			**USA**	
Name			Country	
5000 W OAKEY BLVD STE B7	**Las Vegas**		**NV**	**89146**
Address	City		State	Zip/Postal Code
CORPORATION, INDICATE THE Secretary:				
Vladimir Igor Hernandez			**USA**	
Name			Country	
5000 W OAKEY BLVD STE B7	**Las Vegas**		**NV**	**89146**
Address	City		State	Zip/Postal Code
CORPORATION, INDICATE THE Treasurer:				
Vladimir Igor Hernandez			**USA**	
Name			Country	
5000 W OAKEY BLVD STE B7	**Las Vegas**		**NV**	**89146**
Address	City		State	Zip/Postal Code
CORPORATION, INDICATE THE Director:				
Yailen Matos			**USA**	
Name			Country	
5000 W OAKEY BLVD STE B7	**Las Vegas**		**NV**	**89146**
Address	City		State	Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Vladimir Hernandez
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Secretary
Title

08/21/2024
Date

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

ADVANCE PHARMA
NAME OF ENTITY

NV20222583742
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☑ Corporation
- ☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☐ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
F V Aguilar	E26476352022-6
	Filing Number
	20244269860
Secretary of State	Filed On
State Of Nevada	08/21/2024 15:12:09 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?
- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA2942755	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-07-2023

ADVANCE PHARMA
5000 W OAKEY BLVD STE B7
LAS VEGAS, NV 891463395

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA2942755	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-07-2023

ADVANCE PHARMA
5000 W OAKEY BLVD STE B7
LAS VEGAS, NV 891463395

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ADVANCE PHARMA

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5000 W Oakey Blvd Suite B7

City Las Vegas State Nevada Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-3419316 Website www.advancepharma.us

Licensing Company Email info@advancepharma.us

Section 2: Personal Information

First Richard Middle D. Last Nguyen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address _____

City Las Vegas State Nevada Zip 89103

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF UTAH		08/14 - 08/19	
Address	**City**	**State**	**Zip**
30 2000 E SALT LAKE CITY	SALT LAKE CITY	UTAH	84112
Diploma/Degree obtained, if any			
PHARMD			

School Name		From - To (MM/YY – MM/YY)	
CALIFORNIA STATE UNIVERSITY		08/06- 05/11	
Address	**City**	**State**	**Zip**
1250 BELLFLOWER BLVD	LONG BEACH	CA	90840
Diploma/Degree obtained, if any			
BACHELOR IN BUSINESS			

School Name		From - To (MM/YY – MM/YY)	
FOUNTAIN VALLEY HIGH SCHOOL			
Address	**City**	**State**	**Zip**
17816 BUSHARD ST	FOUNTAIN VALLEY	CA	92708
Diploma/Degree obtained, if any			
HIGH SCHOOL DEGREE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23 - 03/24	[redacted]	LAS VEGAS	NV	89103
09/19 - 07/23	[redacted]	LAS VEGAS	NV	8919
08/14 - 08/19	[redacted]	SALT LAKE CITY	UT	84112
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
WALGREENS PHARMACY			03/21 - 10/22
Business Address	**City**	**State**	**Zip**
6820 W ANN RD	LAS VEGAS	NV	89130
Phone	**Title**	**Number of Employed Hours**	
702-6454106	PHARMACIST	2720	
Description of Duties			
REVIEW AND VERIFY NEW SCRIPTS AND REFILL FOR ACCURANCY			

Business Name			From - To (MM/YY – MM/YY)
SMITH'S PHARMACY			05/15 - 05/18
Business Address	**City**	**State**	**Zip**
876 E 800 S	SALT LAKE CITY	UT	84102
Phone	**Title**	**Number of Employed Hours**	
801-3555257	INTERN PHARMACIST	40 hrs weekly	
Description of Duties			
ASSIST PHARMACIST IN FILLING SCRIPTS, PERFORM INVENTORY MANAGEMENT, DISPENSE PRESCRIPTION TO PATIENTS			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RICHARD D. NGUYEN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/25/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Richard Nguyen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/25/2024

Date

Subscribed and Sworn to before me this 25 day of March, 2024

Notary Public Signature

NOTARY PUBLIC
STATE OF NEVADA
County of Clark
VLADIMIR HERNANDEZ
Appt. No. 16-4403-1
My Appt. Expires Dec. 4, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler ADVANCE PHARMA

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 5000 W. OAKEY BLVD B-7

City LAS VEGAS State NV Zip 89146

Mailing Address (if different from physical address) 5000 W. OAKEY BLVD B-7

City LAS VEGAS State NV Zip 89146

Telephone 702 574 6144 Website ADVANCEPHARMA.US

Licensing Company Email INFO@ADVANCEPHARMA.US

Section 2: Personal Information

First VLADIMIR Middle IGOR Last HERNANDEZ

Alias(es, nicknames, name changes, etc.) VLADIMIR HERNANDEZ PORRAS

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip 89133

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
EXAMFX		03/2016 - 03/2016	
Address	**City**	**State**	**Zip**
ONLINE		NV	
Diploma/Degree obtained, if any			
LIFE AND HEALTH INSURANCE			

School Name		From - To (MM/YY – MM/YY)	
INCAE		02/1992 - 02/1993	
Address	**City**	**State**	**Zip**
MONTEFRESCO	MANAGUA, NICARAGUA	NIC.	
Diploma/Degree obtained, if any			
SALES & MARKETING MANAGEMENT			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSIDAD NACIONAL DE INGENIERIA		02/1987 - 11/1992	
Address	**City**	**State**	**Zip**
COSTADO SUR VILLA PROGRESO	MANAGUA, NICARAGUA	NIC	
Diploma/Degree obtained, if any			
INDUSTRIAL ENGINEENRING			

School Name		From - To (MM/YY – MM/YY)	
INSTITUTO NICARAGUENSE DE ADMINISTRACION PUBLICA		02/1987 - 11/1988	
Address	**City**	**State**	**Zip**
2ND AVE SUROESTE	MANAGUA, NICARAGUA	NIC	
Diploma/Degree obtained, if any			
HUMAN RESOURCE MANAGEMENT			

School Name		From - To (MM/YY – MM/YY	
INSTITUTO NICARAGUENSE DE ADMINISTRACION PUBLICA		02/1987 -11/1988	
Address	**City**	**State**	**Zip**
2ND AVE SUROESTE	MANAGUA, NICARAGUA	NIC	
Diploma/Degree obtained, if any			
BUSINESS MANAGEMENT AND PROBLEMS SOLUTION			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2019 TO PRESE	[redacted]	LAS VEGAS	NV	89107
11/2014 TO 04/2019		LAS VEGAS	NV	89128
02/2012 TO 10/2014		LAS VEGAS	NV	89117

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: TNAM CORPORATION			From - To (MM/YY – MM/YY): 03/2013 TO PRESENT
Business Address: 2917 W. WASHINGTON AVE STE 3	City: LAS VEGAS	State: NV	Zip: 89107
Phone: 702 609 9800	Title: C. E. O		
Description of Duties: MANAGE BUSINESS OPERATION			

Business Name: WASHINGTON TIRES AND ACCESSORIES			From - To (MM/YY – MM/YY): 05/2017 TO PRESENT
Business Address: 2905 W. WASHINGTON AVE	City: LAS VEGAS	State: NV	Zip: 89107
Phone: 702 636 8773	Title: BOOKKEEPER		
Description of Duties: BOOKKEEPER			

Business Name: MASSMUTUAL			From - To (MM/YY – MM/YY): 03/16 - 05/17
Business Address: 1140 N TOWN CENTER DR STE 350	City: LAS VEGAS	State: NV	Zip: 89144
Phone: 702 791 0200	Title: AGENT		
Description of Duties: FINANCIAL SERVICES			

Business Name: BRINI ENTERPRISES			From - To (MM/YY – MM/YY): 11/2004 - 02/2011
Business Address: 3400 CABANA DR UNIT 1099	City: LAS VEGAS	State: NV	Zip: 89122
Phone: N/A	Title: DIRECTOR		
Description of Duties: OPERATION MANAGEMENT			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VLADIMIR HERNANDEZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Vladimir Igor Hernandez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/21/24

Date

State of Nevada, County of Clark

Subscribed and Sworn to before me this 21 day of October, 2024

Notary Public Signature

SERGIO GOMEZ
Notary Public-State of Nevada
Appointment No. 03-79325-1
My Appointment Expires May 17th 2026
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advance Pharma

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04491

Physical Address: 5000 w Oakey blvd Ste B7

City: Las vegas State: NV Zip: 89146

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 7023419316 Website: advancepharma.us

Licensing Company Email: info@advancepharma.us

Section 2: Personal Information

First: Yailen Middle: Last: Matos

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las vegas State: NV Zip: 89108

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Politecnico de la Salud		09/2004-06/2008	
Address	City	State	Zip
Ciudad De Guantanamo	Guantanamo	Guantanar	97800
Diploma/Degree obtained: If any			

School Name		From - To (MM/YY – MM/YY)	
Pre Universitario Vincente Chavez		09/2000-07/2003	
Address	City	State	Zip
Carretera Caimanera	Caimanera	Guantanar	97800
Diploma/Degree obtained: If any			
12 Grade			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained: If any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained: If any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained: If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2024 -present	[redacted]	Las vegas	nv	89108
04/2024-08/2024		Las vegas	nv	89142
09/2021-04/2024		Las vegas	nv	89121
09/2020-09/2021		Louisville	ky	40291
03/2016-09/2020		Las vegas	nv	89121
03/2015-03/2016		Las vegas	nv	89121
01/2014-03/2015		Las vegas	nv	89142
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Brain Health Solutions				From - To (MM/YY – MM/YY): 10/2021-Present
Business Address: 5000 W Oakey blvd STe A2		City: Las vegas	State: NV	Zip: 89146
Phone: 7024763858	Title: Office Manager			
Description of Duties: Office Manager				

Business Name: GE Appliance Part				From - To (MM/YY – MM/YY): 11/2020-09/2021
Business Address: 4000 Buechel Bank Rd		City: Louisville	State: KY	Zip: 40225
Phone: 5024524311	Title: Warehouse Operator			
Description of Duties: Warehouse Operator				

Business Name: Vdara Hotel and Spa				From - To (MM/YY – MM/YY): 03/2016-03/2020
Business Address: 2600 W Harmon Ave		City: Las Vegas	State: NV	Zip: 89158
Phone:	Title: Room Attendant			
Description of Duties: Room Attendant				

Business Name: Aria Hotel				From - To (MM/YY – MM/YY): 02/2014-08/2015
Business Address: 3730 S Las Vegas Blvd		City: Las vegas	State: NV	Zip: 89158
Phone: 8663597757	Title: Room Attendant			
Description of Duties: Room Attendant				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

YAILEN MATOS
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Yailen Matos, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/22/24
Date

Subscribed and Sworn to before me this 22 day of Oct. 2024

Notary Public Signature

NOTARY PUBLIC
STATE OF NEVADA
County of Clark
VLADIMIR FERNANDEZ
Appt. No. 16-4403-1
My Appt. Expires Dec. 4, 2024

(Seal)

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Family primary and specialty care pharmacy

Physical Address: 5550 painted mirage Rd, suite 300

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): 628 N. Hillcrest Rd

City: Beverly Hills State: CA Zip: 90210

Telephone: 310-922-1412 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: dantaheri@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Montemorano

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19839

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Joseph Montemurano	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.012S, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (If any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Family primary and specialty care pharmacy FQHC

Business Name: Family primary and specialty care pharmacy FQHC

Business Address: 5550 painted mirage rd

City: Las Vegas State: NV Zip: 89149

Telephone: [redacted] Email: [redacted]

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Head of the board (title) for Family Primary and Specialty Care (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Daniel Taheri

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/20/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Daniel Taheri hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director/Head of Board (title) for Family primary Specialty care pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

See Attached Certificate

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

Notary Public

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)
County of Los Angeles)

On July 10th, 2024 before me, David S. Andrade, Notary
Date *Here Insert Name and Title of the Officer*

personally appeared Dan P Taheri
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

DAVID S. ANDRADE
Notary Public - California
Los Angeles County
Commission # 2479188
My Comm. Expires Jan 11, 2028

Signature _____
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document
Title or Type of Document: Affidavit for pharmacy license
Document Date: 07/10/2024 Number of Pages:
Signer(s) Other Than Named Above:

Capacity(ies) Claimed by Signer(s)

Signer's Name:
Corporate Officer — Title(s):
Partner — Limited General
Individual Attorney in Fact
Trustee Guardian or Conservator
Other:
Signer Is Representing:

Signer's Name:
Corporate Officer — Title(s):
Partner — Limited General
Individual Attorney in Fact
Trustee Guardian or Conservator
Other:
Signer Is Representing:

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Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Joseph Montemarano Pharmacist Registration #: 19839

Pharmacy Name: Family Primary and Specialty Care Pharmacy

Initial each statement below to indicate you have read and agree with the following:

✓ I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

✓ I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

✓ I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

✓ I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

✓ I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

Date 6/27/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Taheri

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/9/24

Date

Board Use Only	Date Received: 7/15/24	Amount: 500-CK-4695

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC NONPROFIT CORPORATION (82) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Family Primary and Specialty Care Pharmacy** did, on 07/22/2024, file in this office the original Articles of Incorporation-Nonprofit that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/22/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202407224818835
You may verify this certificate
online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Family Primary and Specialty Care Pharmacy

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 5550 Painted Mirage Rd Suite 300

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Juanita Middle: M Last: Stipp

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephon[redacted] Emai[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cimarron-Memorial HS		08/02-06/05	
Address	**City**	**State**	**Zip**
2301 N Tenaya Wy	Las Vegas	NV	89128
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Palo Verde HS		08/05-06/06	
Address	**City**	**State**	**Zip**
333 S Pavilion Center Dr	Las Vegas	NV	89144
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Northwest Career College		08/18-05/19	
Address	**City**	**State**	**Zip**
7398 Smoke Ranch Rd	Las Vegas	NV	89128
Diploma/Degree obtained, if any			
Pharmacy Technician License			

School Name		From - To (MM/YY – MM/YY)	
Arizona College of Nursing		02/24-Present	
Address	**City**	**State**	**Zip**
8363 W. Sunset Rd #200	Las Vegas	NV	89113
Diploma/Degree obtained, if any			
Still in school			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/18-Present	[redacted]	Las Vegas	NV	[redacted]
02/16-02/18		Las Vegas	NV	
08/15-02/16		N. Las Vegas	NV	
02/11-08/15		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Centennial Skin and Cancer Institute			01/2024-Present	
Business Address		**City**	**State**	**Zip**
5550 Painted Mirage Rd Suite #200		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
702-432-3800	Lead Dispensary Technician		40 Hrs/Week	

Description of Duties
Filling prescriptions, billing, Prior authorizations, inventory, refilling, typing, audits, eligibility checks, assisting in dispensary projects, calling patients for information needed, returning expired medications, assisting technicians

Business Name			From - To (MM/YY – MM/YY)	
Sam's Club Pharmacy			11/23-01/24	
Business Address		**City**	**State**	**Zip**
8080 W Tropical Pkwy		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
702-515-7214	Pharmacy Technician		30 Hrs/week	

Description of Duties
Filling prescriptions, billing, Prior authorizations, inventory, refilling medications, filling C2-C5, HIPPA, answering phones, greeting costumers at drop off and pick-up window, money handling,

Business Name			From - To (MM/YY – MM/YY)	
Fort Apache Skin and Cancer Institute			01/2023-10/2023	
Business Address		**City**	**State**	**Zip**
5731 S Fort Apache Rd		Las Vegas	NV	89148
Phone	**Title**		**Number of Employed Hours**	
702-272-1600	Dispensary Technician/Lead Dispensary Technician		40 Hrs/Week	

Description of Duties
Filling prescriptions, billing, Prior authorizations, inventory, refilling, typing, audits, eligibility checks

Business Name			From - To (MM/YY – MM/YY)	
Sav-on Pharmacy			02/20-1/23	
Business Address		**City**	**State**	**Zip**
6730 N. Hualapai Wy		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
702-670-4960	Pharmacy Technician/Lead Pharmacy Technician		40 Hrs/Week	

Description of Duties
Filling, inventory, ordering, vaccine certification, administered vaccines from ages 5 and older, Prior authorizations, answered phones, greeted costumers, typed, returned expired medications, HIPPA

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy- Target			8/19-2/23	
Business Address		**City**	**State**	**Zip**
8750 W. Charleston Blvd		Las Vegas	NV	89117
Phone	**Title**		**Number of Employed Hours**	
702-933-2315	Pharmacy Technician		20 hrs/week	

Description of Duties
Filling, answering phones, HIPPA, inventory, greeted costumers, typed, traveled to other pharmacies, removed expired medications from shelves, assisted pharmacist in other pharmacy duties.

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Juanita Stipp, **certify that as the designated representative for**

Family Primary and Specialty Care Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JS I am at least 21 years of age;
3. JS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Juanita Stipp

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/02/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Juanita Stipp

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/02/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Juanita Stipp, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/2/24

Date

Subscribed and Sworn to before me this 2nd day of August, 2024

Notary Public Signature

BECKY BROWN
Notary Public, State of Nevada
Appointment No. 01-70764-1
My Appt. Expires Sep 24, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Family primary and Specialty care pharmacy
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):
Physical Address: 5550 Painted Mirage Road
City: Las Vegas State: NV Zip: 89149
Mailing Address (if different from physical address): 415 Walker Drive
City: Beverly Hills State: CA Zip: 90210
Telephone: 310-880-5519 Website: [redacted]
Licensing Company Email: EC@FPSCpharmacy.com / www.FPSCPharmacy.com

Section 2: Personal Information

First: Elise Middle: monica Last: Cameron
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X
Mailing Address: [redacted]
City: Beverly Hills
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		09/98 - 01/2~~0~~	
Address: 660 S. Mill Ave.	City: Tempe	State: AZ	Zip: 85281
Diploma/Degree obtained, if any: Bachelor of Science Business Management			

School Name		From - To (MM/YY – MM/YY)	
Yavapai College		09/95 - 06/98	
Address: 601 Black Hills Drive	City: Clarkdale	State: AZ	Zip: 86324
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
Sedona Red Rock High School		09/94 - 06/95	
Address: 995 Upper Red Rock Loop Rd	City: Sedona	State: AZ	Zip: 86336
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/17 -	[redacted]	Los Angeles,	CA	[redacted]
11/14 - 10/17		Beverly Hills	CA	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Christie's International Real Estate - AKG			From - To (MM/YY – MM/YY): 02/23 - present	
Business Address: 433 N Camden Dr	City: Beverly Hills		State: CA	Zip: 90210
Phone: 310. 893. 8300	Title: Agent			
Description of Duties: Buying and selling properties on behalf of clients				

Business Name: Self employed			From - To (MM/YY – MM/YY): 01/14 - 01/23	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elise Cameron

Print Name (First, Last)

Elise Cameron — 11/13/24

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Elise Cameron, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Elise Cameron — 11/13/24

Original Signature — **Date**

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 13th *Date* day of November *Month*, 20 24 *Year*, by

(1) Elise Cameron

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

GREGORY LOPEZ
Notary Public - California
Los Angeles County
Commission # 2475413
My Comm. Expires Dec 5, 2027

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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Candy Nally

From: Daniel Taheri [redacted]
Sent: Tuesday, November 19, 2024 10:14 AM
To: Pharmacy Licensing
Cc: Candy Nally
Subject: Re: Personal History
Attachments: fqhc resumes 082724.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

gm, just making sure that you received this.
please see complete list of board members as it stands today. thank you

please see attached for resumes:

Fara Moshfegh - patient
farshad lavian - patient
bob shiepe - patient
roberto santana
trai Huu
francisco santana
alba martinez
gavin cain - patient
cristal tsen - patient

On Mon, Nov 18, 2024 at 7:48 AM Pharmacy Licensing <Pharmacylicensing@pharmacy.nv.gov> wrote:

Hi Dr. Taheri,

Thank you for the updates. I believe you indicated that several individuals sit on the board of the foundation. Can you supply a list of the board members to be included as part of the application?

Kind Regards,

Mark Sedar

COO

*not

On Wed, Nov 13, 2024 at 7:50 AM Daniel Taheri [redacted] wrote:

gm, can i get a copy of the regulations for the personal history form so we can make sure who does not qualify to be on this?

Any board member qualifies long as they are not a medical professional? Any other restrictions? We just want to make sure we are doing this correctly.

There are 11 board members for this nonprofit. thank you again.

On Tue, Nov 12, 2024 at 1:23 PM Olivia Mora <o.mora@pharmacy.nv.gov> wrote:

Hello,

Please see attached Personal History application.

Gmail [redacted]

Fara Moshfegh

Fara Moshfegh [redacted]
To: Daniel Tahe[redacted]

Fri, Aug 23, 2024 at 5:33 PM

Fara Moshfegh is a custom home builder and real estate developer associated with both Amiel Construction Inc and Cellbright Services Inc. He has a strong presence in some of the most exclusive neighborhoods of Los Angeles. Fara holds a Bachelor of Science in Business Administration, majoring in Industrial Management with a minor in Economics and Accounting. Fara has developed numerous condominiums and apartment buildings and serves as a general contractor specializing in custom homes and large-scale residential projects.
His entrepreneurial acumen extends beyond construction. Fara owned and operated FM and Associates, a brokerage firm specializing in full-service car washes, as well as a seasoned escrow company. He also owned Ambassador Car Wash in Los Angeles and currently owns multiple apartment buildings in Hollywood in the broader Los Angeles area. Fara is presently focused on the development of a 150-unit hotel on Whitley Ave in Hollywood, demonstrating his ongoing commitment to shaping the city.

Best

FARSHAD LAVIAN

[redacted]

Beverly Hills, CA [redacted]

SUMMARY

Medical Administrative professional with expertise include planning, project management, account management, clinical documentation, medical coding, auditing, sales, market analysis, territory management and customer service. Responsible, detail oriented with strong organizational, analytical, problem solving, communication and relationship management skills.

PROFESSIONAL EXPERIENCE

SURGICAL ALLY INC **2024**
Director of operation & admin.

Surgical 1st assist to multiple major hospitals and private practices.

In charge of managing a team of Physician assistants and Nurse practitioners assisting in Surgeries & clinical assist.

PRIME HEALTHCARE HOSPITAL, Los Angeles, CA 2015 - 2018
Clinical Documentation Specialist, CDS

- Reviewed and analyzed documentation in the medical record for both inpatient and outpatient visits to ensure accuracy of diagnosis and procedure codes assigned by the Coders, Clinical Documentation Specialists (CDS) or Computer Assisted Coding (CAC) software.
- Finalized the coding and abstracting of the medical record upon ensuring the assignment of International Classifications of Diseases, Ninth Revision (ICD-9-CM) and Tenth revision (ICD-10/PCS), Current Procedural Terminology (CPT), and Health Care Procedure Coding System (HCPCS).
- Led Case Management, created Admission Criteria Form (ACF) and Interquals (IQC's).
- Coordinated with the medical staff to facilitate appropriate clinical documentation of patient care.

- Reviewed documentation for inpatient admission criteria, initial and extended-stay concurrent reviews on all selected admissions and documented findings.

CANTURY WELLNESS CERNTER, Los Angeles, CA
2011 - 2015
Director of operation & admin.

- Led executed sales and marketing initiatives.
- Developed and administered a $150,000 marketing budget.
- Managed product positioning, communication planning, advertising and public relations for two offices.

- Generated $1 million+ annually.
- Used ICD9-CM.

SKY DENTAL SALES, Los Angeles, CA 2009 - 2011
Vice President and Regional Sales Director

- Led a team of 12 employees of sale professionals.
- Sold to dentists and dental offices.
- Increased sales 80%
- Generated up to $300,000 annually.
- Closed individual sales valued to $90,000.
- Increased sales by switching marketing strategies and optimizing internet sales.

KLM MANAGEMENT GROUP, Los Angeles, CA 2007 - 2009
Director of Sales

- Supervised, trained and mentored 20 sales professionals.
- Generated up to $2 million annually.
- Managed 30 major accounts, Captured 15 new accounts

MEDICAL SCHOOL 2001 – 2006
Student

EDUCATION

MD, Universidad Autónoma de Guadalajara School of Medicine, San Antonio, TX 2005

Internship, University of Chicago, St. Anthony's Hospital 2005 - 2006

COMPUTERS

Microsoft Word, Excel and PowerPoint

LANGUAGES

English, Spanish, and Farsi

Robert Shiepe
Los Angeles, CA
[redacted]

Professional Summary

Innovative and dedicated pharmacist with over 25 years of pioneering work in HIV/AIDS research and treatment. Founded the first mail order pharmacy in the U.S. and made significant contributions to extending patient lives through novel research involving sulfur-rich N-Acetylcysteine (NAC). Currently engaged in private consulting for surgery centers and advanced astronomy photography. Active supporter of global animal welfare initiatives.

Education

University of Wyoming, School of Pharmacy
Doctor of Pharmacy , 1982

Professional Experience

Founder & CEO
Bob's Pharmacy - *Private Pharmacy and Mail Order Service*
Los Angeles, CA
1986 – 2012

Established the first mail order pharmacy in the U.S.
Pioneered research in HIV/AIDS treatment, significantly contributing to the field with novel approaches using sulfur-rich N-Acetylcysteine (NAC).
Successfully treated over 5,000 patients, extending the lives of many through advanced pharmaceutical interventions.

Private Consultant
Surgery Centers
Los Angeles, CA
2012 – Present

Provide expert consulting services to surgery centers, leveraging extensive pharmaceutical knowledge and experience.

Achievements

- **Medical Patent:** Issued in 2022 for innovative pharmaceutical methods.
- **HIV/AIDS Research:** Contributed groundbreaking research in the field, utilizing sulfur-rich NAC.
- **Pharmacy Innovation:** Introduced and successfully managed the first mail order pharmacy in the United States.
-

Interests

- **Advanced Astronomy:** Engaged in new methods of astronomical photography.

- **Charitable Work:** Active in global animal welfare organizations, supporting various initiatives for animal protection.

[redacted] Compton, CA 90220 [redacted]

Alba A. Martinez

Summary

Over fifteen years of hands-on experience in Healthcare Contracting and Credentialing with knowledge in Managed Care, Physician Dispensaries, ASCs, and Laboratory. Effective leader and problem-solver dedicated to streamlining operations to decrease costs and promote organizational efficiency across various departments. Can efficiently multitask multiple projects and execute.

Experience

Oct. 2023 – Present | RJ Imaging | Valencia, CA

Medical Billing/ Contracting Manager - *Radiology*

- Help set up the new group with medical contract, vendors and billing software
- Generate revenue by making payment arrangements, collecting accounts and processing claims
- Monitor, respond, and ensure provider applications are submitted to health plans.
- Maintain relationship with health plans Provider Relation Reps.
- Conducts audits to ensure AR is low
- Perform posting charges

Oct. 2019 – Sept. 2023 | LA Laser Center PC/ Skin and Cancer Institute | Redondo Beach, CA

Credentialing Manager - *Dermatology*

Completed provider & ASC credentialing and re credentialing applications, monitors applications, and follow up, using CAQH, CPPA apps, PECOS, PAVE, AHCCCS, etc. in various states.
Set up and kept provider information in various systems and databases.
Responsible for setting up new clinics and creating new business ventures.
Credential physician dispensaries, with Wholesalers, PBMs, PSAO, etc. and apply for licenses.
Maintained corporate provider contract files and served as liaison between health plan and the billing department.
Assisted the Director of RCM/Billing Department with claims denials research and provided information on whether we are in-network with specific products, and other miscellaneous billing and collections issues.
Submitted Letter of Intend to potential health plan, as needed.
First point contact for contract negotiations and renegotiations
Audit health plans directories for current and accurate provider information.
Acquired all business licenses and permits for locations.
Maintain knowledge of current health plan and state agencies to remain compliant.
Made EFT updates/changes.
Applied and maintained licenses with the Medical Board and Pharmacy Board for providers and group.
Supervised the credentialing department.
Ability to take responsibility and make decisions within the scope of authority.

Apr. 2007 – Feb. 2020 | Harbor-UCLA Medical Foundation, Inc. | Torrance, CA

Contracts and Credentials, Coordinator/ Payroll/HR Administrator – *Multispecialty*

- Reviewed all employee new hires and termination files, to ensure complete and accurate documents were obtained.
- Supervised and managed the payroll functions for three entities.
- Assisted the VP of Human Resources with the onboarding and off boarding checklist.
- Worked closely with the VP of HR to monitor new laws and regulations.
- First point contact for contract negotiations
- Review and maintain all contracts/agreements, while maintaining a close relationship with health plans managers and representatives.
- Subcontracted to assist the Medical Staff Office at Harbor-UCLA Medical Center for various projects.
- Screened practitioner's applications and their supported documentation to determine the accuracy of their qualifications, and to determine if any open reprimand has been reported, to the following: Breeze, DEA, American Board of Medical Specialties, etc.

- Managed the ongoing monitoring of potential external sanction pertaining to the faculty, the process encompassed the following Medicare, Medi-Cal and State and Federal Sanctions, Malpractice cases, OIG, etc.
- Responsible for collecting, entering, organizing, and submitting data for provider and facility enrollment with various health plans, including CAQH system.
- Reviewed applications for completeness, flag missing information and signatures before sending the pre-populated application for providers to complete.
- Processed and submitted applications for payer approval.
- Overseen CMS enrollment, revalidation, and disenrollment applications, per CMS guidelines.
- Credentialed and re-credential providers as required by health plans, hospitals, and government agencies.
- Worked closely with the billing department to resolve any provider enrollment or contractual issues, and assist with running eligibility, registration, etc. Also, abetted with the medical office with any complex authorization prior to the patient visit.
- Provided support to the Chief Executive Officer, VP of HR, and group physicians.

Sept. 2006 - Mar. 2007 National Store, Inc. Gardena, CA

Real Estate Administrator Assistant

Jun. 2004 - Aug. 2006 Big 5 Sporting Goods Corp. El Segundo, CA

Management Information System Admin. Assistant

Education

University of Phoenix –Associate in Business

Francisco R. Santana

[redacted]

Objective

In search of an opportunity as a Medical Practice Manager in a healthcare facility where over 20 years of medical experience in leadership, logistics and patient protocols can propel an organization to its maximum potential.

Professional Experience

Skin and Cancer Institute **07/2022 – Present**

Senior Manager

Responsible for 20 locations within California, Nevada and Arizona, overseeing on-site managers and providers covering daily dermatological clinical operations. Recruit, hire, and train new employees both remotely and in person. Build provider schedules and grant staff administrative access to IT systems. Keep in constant communication with managers and medical providers, including monitoring employee performance, disciplinary action, and terminations. Approve payroll and ensure overtime and break compliance. Perform annual reviews. Oversee supply inventory. Act as liaison between CEO and all other departments. Manage compliance with all necessary state and local regulations including CLIA laboratory evaluations. Serve as primary contact for opening 3 new clinic locations including site selection, construction, marketing, and operating logistics. Review customer feedback and respond to escalated complaints and concerns.

Palm Desert Dermatology & Skin Cancer **09/2021 – 07/2022**

Office Manager

Lake Havasu Dermatology & Skin Cancer **11/2020 – 09/2021**

Office Manager

Managed day to day operations at co-owned locations including scheduling patients, entering patient data into EHR (EMA) system, answering multi-line phone system, assisting physician in-office exams, chart preparation, preparing clinic for audit, ordering back/front office supplies, in-office clean up, payroll using Paycom, acting as a medical assistant when needed, and office productivity reporting. Wrote employee reviews and employee disciplinary action. Created office logs and new hire onboarding. Traveled to different clinics within the organization to assist, train, and facilitate new location openings.

California Nurses Educational Institute **01/2018 – 04/2023**

Medical Office Administration – Instructor (Part Time)

Instructed students on all aspects of Medical Office Administration, assigned reading material and homework, prepared quizzes according to lecture and reading material, led lectures according to school's syllabus, and provided career counseling.

Sandra Bender, MD **02/2017 – 07/2020**

Office Manager / Medical Assistant / Front Office Receptionist

Managed daily operations, scheduled patients, verified insurance, collected payments, entered patient data into EHR (Practice Fusion) system, assisted physician with all requests, prepared patient charts, and maintained medical records.

Eisenhower Desert Orthopedic Center **05/2016 – 08/2016**

Clinical Manager

Oversaw 23 employees, supporting 10 Physicians and 10 Physician Assistants. Processed payroll in Kronos. EMR/PM (NextGen) patient database administration. Performed employee reviews. Addressed patient concerns. Ordered back-office supplies. Wrote back-office training guide. Implemented customer service training manual. Worked with other managers to create a better clinical flow for all locations through team building with monthly meetings and employee counseling.

West Dermatology **09/2015 – 05/2016**

Office Manager

Managed 19 employees and supported 4 Physicians and 4 Physician Assistants. Processed payroll in ADP. EMR (NextGen) patient database administration. Assisted with MOH's clinic (minor surgeries in office). Other duties included audit compliance, employee counseling, employee reviews, scheduling patients, and processing insurance and payments.

Desert Region Internal Medicine **02/2014 – 09/2015**

Clinical Supervisor / Medical Assistant

Supervised a team of 7 Medical Assistants and Front Office Personnel by conducting yearly employee evaluations, handling patient complaints, EHR/EPM using NextGen system, scheduling patients, preparing charts, translating for Physicians, verifying insurance, and obtaining prior authorization for medications and procedures.

Institute of Orthopedics Desert Regional Medical Center **07/2002 – 02/2014**

Back Office Clinical Supervisor / Medical Assistant

Managed staff of 18 Medical Assistants in a union environment. Processed referrals and obtained prior authorizations. Scheduled surgeries. Obtained patient information and vitals (blood pressure, temperature, O2, weight, height, and pulse).

Administrative Medical Front Office Skills

Bilingual – Spanish	Telephone Triage	Customer Relations
Supply Acquisition Management	Bookkeeping	Filing / Scanning
Insurance Verification	ICD-10 Coding	CPT Coding
Referral Processing	Appointment Scheduling	Surgery Scheduling
Patient Registration	Knowledge in Cerner	Worker's Compensation
Payroll Processing	EMA Derm Charting	Acumatica (POS system)

Medical Back Office Skills

Culture Processing	Surgical Tray Set-Up	Venipuncture
Blood Chemistries	Physical Therapy Modalities	EKG's
Current CPR & BLS	Exam Room Preparation	Wound Care
Patient Positioning & Draping	Assisting in MOHs Surgery	Urinalysis

Vitamin Injections to patient (B12, Vitamin D, B6, Testosterone)
Vitals (Blood Pressure, Pulse, Temperature, O2, Respiration)

Education

College of the Desert, Palm Desert, CA	General Education
Skadron College, San Bernardino, CA	Medical Assistant Certificate
Crafton Hills College, Yucaipa, CA	General Education
Beaumont High School, Beaumont, CA	High School Diploma

TRAI HUU

Experienced IT leader with top-notch implementation and project management abilities. Highly organized, methodical and skilled at building consensus across high-performance teams. Well-versed in Automotive industry, Medical Field, Aerospace industry planning and deployment.

Manages and prioritizes workload, demonstrates ability to multi-task; Possesses strong analytical skills, demonstrates a customer orientation; strength in analytical & math and reasoning skills, effectively communicates verbally and in writing. 24 years experienced in IT relate field as IT Director / Project Director. Sr. Mission-focused Scrum Master with extensive experience coaching and mentoring highly capable teams. Bilingual professional with more than 16 years of experience delegating tasks and managing projects.

Work History

2019- 2023

IT North America Manager of Supply Chain

***Nordstrom**, CA Riverside, Ontario, San Bernardino*
Nordstrom Fashion retailer supporting West coast supply chain locations.
North America IT Manager

- Managing 12 Supply Chain Location for Nordstrom across West Coast, Mid-West, East Coast. Six Distribution sites and Four Fulfillment Center and two Omni Centers.
- Warehouse Systems – Manhattan Associates, High Jump, Dematic West
- Warehouse MHE – Dematic, Wynright, SDI
- I manage to build Nordstrom fist ever Omnichannel building in Riverside CA. 2.8 Mill SF. Omnichannel max output daily 500,000 units.
- Full Automation process using Dematic System and WES Manage warehouse software.
- I created warehouse strategies using waterfall and agile methodology.
- 47 IT Ops technicians reported to me in the Southern CA. From Tech 1 to Engineering Level SR and 3 PMO
- Prepare RFPs, bid proposals, contracts, scope of work reports. Negotiate with vendors, outsourcers,

Personal Info

Address

[redacted]

Garden Grove, CA, 92842

[redacted]

Skills

Service Now Cert

CCNA 2017 Cert

Azure 2017 Cert

Exchange 2017 Cert

Office 365 2016

SolarWinds ArcGis 2017

Six Sigma 2017 Cert

ITIL Cert V4 HRIS

Juniper 2017

and contractors to secure infrastructure-specific products and service.

NetSuite 2018

Atlassian Jira Suite

- Research and deploy RFID technologies.
- Zebra and Printronix Support
- Operation Support inbound and outbound
- Daily customization reporting using SSR Reporting / SQL for corporate using Tableau
- Metabase dashboard build "live time monitor"
- ServiceNow Admin Ticket System
- Jira "Project Management" Confluence
- MDM Admin
- Act as industry engineer when needed.
- Building simulation / forecast models
- User Assessment Testing
- Currently refreshing network infrastructure and building standardization across other FC / DC
- 2.8 Million hardware refreshes.
- Managing FC, DC , Omni Budgets
- Building another 2,8 million sf Omni center in Seattle Washington 2022.

IT Director

The Le Group, Huntington Beach, CA

2018-2020

The Le Group is a primarily e-commerce company comprised of three different businesses with offices in Orange County and a manufacturing warehouse located in Vernon, California and Beijing China

IT Director

- Lead the initiative to develop and implement a global IT risk assessment framework that will be used across jurisdictions
- Identify and evaluate IT risks and provide recommendation for process, control or security enhancements needed to risk mitigation
- Development and implementation of policies and processes for data governance to ensure the security of protected and sensitive data (PCI, PII, GDPR, PHI, HIPPA
- Agile methodologies able to run scrum ceremonies

- Prepare RFPs, bid proposals, contracts, scope of work reports. Negotiate with vendors, outsourcers, and contractors to secure infrastructure-specific products and service
- Salesforce role out and deployment
- Negotiate and execute contracts on behalf of the company
- Develop and implement Ecommerce merchandising strategy across multiple brands and marketplaces (Amazon, Ebay, Walmart, Shopify"
- Drive efficiency across all marketplace's businesses (supply chain, advertising, customer service.
- Built company network and security from the ground up making it scalable for future enterprise expansion and PCI compliance.
- Company runs on a cloud-based system utilizing Office 365 and Azure on an AWS platform. AWS hosts The Le Group's three main websites I created using managento.
- Built manufacturing warehouse's ERP system NetSuite and MRP system called SAP along with a NetSuite consultant.
- Managed warehous , inventory system and logistics setup.
- Built company call center using Zendesk and Nextiva.
- Attended daily management meetings.
- Created quarterly budget and sales/manufacturing forecasts.
- Established client relations with our business partners in China and Vietnam.
- Collaborated with management, technical crew members and fellow supervisors to organize efficient site operations and achieve demanding schedule targets.
- Monitored network activates for possible performance issues.
- Monitored social media and online sources for industry trends.

- The following departments reported to me directly: Information Technology, social media, and Human

- Carried out company-wide recruitment and termination.
- Created company Human Resource Information System (HRIS) and employee handbook.
- Worked closely with company's legal advisory board.
- Managed quality assurance program including on site evaluations, internal audits, and customer surveys.
- Prepared relevant SRM documents in conformance with Safety Management System (SMS) order.
- Mediated staff conflicts and coached staff as needed to resolve performance issues.
- Devoted special emphasis to punctuality and worked to maintain outstanding attendance record, consistently arriving to work early, ready to start immediately.
- Liaised between multiple business divisions to improve communications.
- Utilized compliance tools, corrective actions and identification of deficiencies to mitigate audit risks.
- Built external tools to automate program operations and ensure user-friendly implementation and created and implemented payroll and letter delivery processes.
- Educated management on successful approaches for enhancing policy implementation and enforcement to prevent legal entanglements involving employees.
- Served as representative in various civic and community functions to further enhance company image and develop additional business.
- Built 1mill SF automation warehouse with GreyOrange Automation

2008-2018

Global Field Engineer Director

***TESLA**, Fremont, CA*

- supporting 516 Tesla facilities which included solar warehouse, HQ, Tesla service centers, Tesla retail stores, Critical Sites.
- Tier 3 & 4 support responsible for providing technical support to end-user and management by answering complex questions on functionality and product usage via web, phone, chat and email.
- Also responsible for recreating customer problems and collaborating with other parts of the organization to bring resolution for staff.
- Ability to provide 24x7 on-call Support for Network outages + Event management.
- Executive Support Including Elon.M / Family
- Work remotely and independently maintain regular written and in-person communication with decision-makers stakeholders, department heads and local IT Managers regarding pertinent infrastructure activates.
- SCCM Admin / Airwatch MDM Admin
- Jira Project Management
- Infosec support / deployment
- Salesforce CRM Admin / deployment
- Testing and deploying hardware among service center and retail location.
- Project Management conduct feasibly studies for various upgrade.
- Travel quarter to perform regional health check.
- Lead contact during network / critical outages.
- Identify bottlenecks in departmental business function and initiate corrective action through influences and reporting.
- Assist with Site build and remodels.
- Ensure the integrity of the internal and external network.
- Responsible to document works, and report or coordinates efforts with partners, management and other team members.

- Communicate information about network changes, issues and problems through proper channels to appropriate personnel.
- Work with Regional operation manager to plan quarterly project and budget.
- Inventory management.
- Met with customers to resolve issues and build productive relationships.
- My Team did new service location / retail build along with site refreshes. Across NA and Apec
- Manage 24 Global Employees
- Managed workover and completions engineering assignments and operator's completion plan.
- Investigated, compiled and modeled information for detailed project proposals.
- Kept site work safe and in line with budget, schedule and applicable building codes.
- Utilized pipe and filter model to find bottlenecks and enable measurement of system resource usage and process behavior at boundary limits of all operations.

2005-04 - 2011-05

SR IT Manager

Skechers, Manhattan Beach, CA

- Project Director Retail store deployment "New site / remodels
- Supporting 376 Retail location across the globe
- WMS Upgrade + MHE
- Automation Warehouse SDI
- Negotiate and execute contracts on behalf of the company
- Generate, manage and close sales leads generated from company and personal referral sources.
- Provide project information to all project manager and project accountant including budget, completion date to ensure production team understands scope of budget and schedule.
- Accounts receivable

- Areas of responsibilities included servers, internet, network applications, LAN/WAN connectivity, security, antivirus.
- Process backup tapes for Windows servers, ensuring backup process is ready for nightly processing.
- Maintain email servers, storage array, and troubleshot Active Directory and Group Policies.
- Other responsibilities included Domain Migration, Windows 2000 migration to XP, project management and implementation of applications, hardware and network equipment.
- Troubleshot Unix in regarding command, disk I/O, CPU usage, load and network connection.
- Responsible for various desktop/laptop related activities included hardware installation, printer server, software configuration, upgrade, migration, application support, printer server and network connectivity.
- Working knowledge with MAC's application compatibility and the time support users Iphone and Ipaq.
- Developed project control roadmap to guide various projects.
- Orchestrated wide range of projects, improvement strategies, changes implementation, new revenue stream establishment, and creative marketing and advertising.
- Managed budget implementations, employee reviews, training, schedules and contract negotiations.
- Improved brand awareness by monitoring all marketing campaigns and fostering membership acquisitions and business development.
- Established and administered annual budget with effective controls to prevent overages, minimize burn rate and support sustainability objectives.
- Applied performance data to evaluate and improve operations, target to current business conditions and forecast needs.

2009-05 - 2015-05

IT DIRECTOR

INTEGRO HEALTHCARE

- Supporting 92 Skill nursing and Assisted living community within the United States.
- Managing and budgeting IT / Cap-EX Projects.
- Managed 22 IT individuals "Helpdesk, Desktop Support, System Admin, DBA,.
- EHR / EMR System Deployment "Epic " Point- Click Care
- Managed/supported enterprise data center systems, technical support and maintain virtualized environments 6,000 user base on Windows/Linux/AS 400/Mac OS X platforms.
- Installed and completed Cisco Call Management Systems / Voip systems.
- Responsible for various desktop/laptop related activities included hardware installation, software configuration, upgrade, migration, application support, printer server and network connectivity.
- Extensive experience ADFS 2.0, Active Directory (add/remove accounts, privileges, GPOs, group access).
- Working experience with clustering, WINS, Veritas, DNS, DHCP, SAN storage for daily backup and disaster recovery.
- Working experienced and knowledge with Hyper-V, Webs Servers, NetApp, Load Balancers, Cloud Computing: Google Apps and McAfee Host Security.
- Working experienced in Windows 7 Deployment, Image Development and deployment with (MDT, SCCM, ITIL OSD) very familiarity with application packaging processes.
- CRM Salesforce custom data reporting, Sales analytical and profit margining.
- Working knowledge with MAC's application compatibility and the time support users Iphone and Ipad.
- Cap-Ex Management, Project Manager EHR.

- Working knowledge of telecom equipment such as voice switches, VOIP and traditional systems.
- Utilize MS Systems Configuration Center Manager to provide remote control, patch management, software distribution, operating system deployment, network access protection and hardware and software inventory.
- The same time using MS System Center to delivers management for Windows Server environments that critical business applications run on.
- Help optimize performance and availability for Microsoft workloads like Exchange, SQL, and SharePoint.
- Utilizing Citrix ZenCenter to providing VPN support and account login relate.
- Working on the project of File Servers and MS Exchange Migration.
- Communicate and coordinate with client groups to assess their needs and develop and implement application.
- Responsible for the design and implementation of the IT environment associated with the upcoming expansion of the business.
- Manage and optimize infrastructure assets to satisfy internal financial targets.
- Performed detailed assessments of risks to determine constraints and develop mitigation strategies.
- Investigated and corrected or escalated project problems.
- Gathered requirements, defined scopes, allocated resources and established schedules meeting or exceeding project demands.
- Managed quality assurance program including on site evaluations, internal audits and customer surveys.
- Performed various administrative functions, including filing paperwork, delivering mail, sorting mail, office cleaning and bookkeeping.
- Monitored social media and online sources for industry trends.

- Negotiated agreements between employees to clarify misunderstood directions and resolve conflicts affecting performance.

1999-09 - 2005-05

SYSTEMS ADMIN/SR. DESKTOP SUPPORT Manager

Toyota, Torrance, CA

- Supporting 22,000 US retail shoes and 300 overseas stores "POS".
- Managed and supported 10 helpdesk and 3 client services.
- Managed/supported enterprise data center systems and service desk (Tier II, III) technical support and maintain virtualized environments 1,500 user base on Windows/Linux/AS 400/Mac OS X platforms (supported 15 western regional locations).
- Extensive experience ADFS 2.0, Active Directory (add/remove accounts, privileges, GPOs, group access).
- SMS to push out packages, Symantec Ghost imaging.
- MS Exchange 2010 maintains email servers, storage array; set up mailboxes, distribution lists.
- Working Experience with VMware ESXi 5.0/Hyper-V, Citrix Farm, LAN Oracle, SQL Database Server, Dell/HP Blade Servers rebuilt/configured/maintained/troubleshoot.
- Working knowledge of IBM iSeries5 AS400 system, Windows Server 2003/2008 R2/2012 enterprise production as well as QA and development.
- Working knowledge of Hyper-V, Webs Servers, NetApp, Load Balancers, Cloud Computing: Google Apps and McAfee Host Security.
- Working experienced in Windows 7 Deployment, Image Development and deployment with (MDT, SCCM OSD) very familiarity with application packaging processes.
- Working knowledge of telecom equipment such as voice switches, VOIP and traditional systems.

- Working knowledge with MAC's application compatibility and the time support users iPhone and iPad.
- Working experience with clustering, WINS, Veritas, DNS, DHCP, SAN storage for daily backup and disaster recovery.
- Ticketing Systems: Remedy, Peregrine.
- Responsible for ensuring all I.S.
- infrastructure is fully operational prior to start of Warehouse shift.

Education

2004-01

Bachelor of Science: Information Technology

UCR Riverside, CA

2006-2008

UCLA CA

Master of Business Administration

UCLA Anderson School of Management

MBA 2010

Whittier Law School

Bar Exam Passed

High School Diploma

Redlands High School - Redlands, CA

Board Advisory

Philz Coffee and SpaceX

Roberto Santana

[redacted] Long Beach, CA [redacted] | [redacted]

Education

Franklin W. Olin College of Engineering (Olin College), Needham, MA 09/2005 – 06/2010

Bachelors of Science in General Engineering

Concentration in Systems (major courses as follow):

Computer Architecture	Controls	Differential Equations	Dynamics	Linear Algebra
Linear Dynamics and Chaos	Systems	Thermodynamics	User Oriented Collaborative Design	

California Academy of Mathematics and Science, Carson, CA 09/2001 – 06/2005

High School Diploma

FIRST Robotics Team #687 member for 4 years, Team Leader for 3 years

Experience

Canton Food Company, Los Angeles, CA 2017-Present

Assistant Inventory Specialist

- Coordinate with company buyers regarding the day to day changes to products, including pricing, brand, packing and description changes.
- Generate product information labeling and signage and oversee the collection and destruction of all old materials
- Inventory database administration and upkeep
- Photograph and catalog all existing and incoming products
- Responsible for implementing short term sales and providing store personnel with sale signs and labels

M&N Manufacturing, Paramount, CA 2015-2017

Manufacturing Engineer

- Designed informational brochures for distribution to potential clients.
- Researched and contacted companies with need for company services and traveled to local companies to establish relationships with prospective customers.
- Assisted customers in design modification to reduce manufacturing time and cost.
- Used SolidWorks and Mastercam software to model parts, draft drawings, and create machining procedures.

GDA Enterprises, Gardena, CA 2013 – 2015

Full Stack Developer

- Designed the sales website following the CEO's specifications which included a full catalog, user logins, shopping cart, and database of sales information.
- Worked with company salespeople to keep the website up-to-date with new products and promotions.
- Used various computer programming languages such as HTML, CSS, SQL, PHP, JavaScript (and jQuery).

Self-Employed, Long Beach, CA 2011 – Present

Private Tutor

- Provided individualized instruction to local college students in subjects such as physics, calculus, and statistics resulting in a minimum of one letter grade improvement for all students.

Ay Jalisco Mexican Restaurant, McAllen, TX 2010 – 2011

Assistant Manager

- Recruited, interviewed and supervised employees in customer service and point of sale (POS) customer transactions.
- Responsible for addressing customer service issues and disputes to ensure customer satisfaction and return business.
- Responsible for maintaining restaurant computer systems and for diagnosing and resolving system errors.
- Designed promotional brochures used to market to local businesses.

Woods Hole Oceanographic Institution (WHOI), Needham, MA 10/2008 – 05/2009

Assistant Programmer

- Worked as a member of a team of five individuals, through Olin College's Senior Capstone Program in Engineering (SCOPE) to create a program for WHOI to use in the scheduling of their ocean buoys.
- Used the Python language to write a program that simulated the power consumed and generated on a scientific buoy. The program data was analyzed by WHOI researchers and used to revise the schedule of measurements and testing done on the ocean buoy.
- Wrote the program documentation, a detailed manual providing a description of all variables, attributes, methods, algorithms, and files contained in the program for WHOI researchers to understand and revise.
- Managed the project's completion schedule and presented weekly PowerPoint presentations to project coordinators at WHOI.

Northrop Grumman Space Technology, Redondo Beach, CA Summers 2005 & 2006

Systems Engineering Intern

- Assisted Nanci Shawger, Systems Engineer for the Space Interferometry Mission (SIM), a joint project with NASA tasked with designing, building, and launching a satellite to accurately measure the position of celestial objects.
- Developed a 3D model of the satellite for use in mission simulation of satellite motion, articulation, and telecommunication.
- Used the Systems Tool Kit Software Suite (a modeling program used by SIM) to simulate the position of the satellite and its components over a five and a half year time span. Verified successful lines of sight during communication periods and correct positioning for desired measurements. Recommended changes to the scenario wherever discrepancies in satellite positioning were found.

University of Illinois at Chicago (UIC), Chicago, IL Summer 2004

Student Research Assistant

- Worked in the lab of R. John Solaro, PhD, on research testing whether a genetic modification could reduce the damaging effects of heart attacks on heart muscle.
- Responsible for conducting force transduction experiments on mouse heart muscle fibers and analyzing the results.
- Published an abstract entitled "Sarcomere Length-Dependent Activation in Ischemia Reperfusion" in the *Journal of the Association of Academic Minority Physicians* Vol. 15, (Summer).
- Awarded First Place in the UIC Summer Science Fair.

Temple University, Philadelphia, PA Summers 2002 & 2003

Student Research Assistant

- Worked with Michael Autieri, PhD, and his lab on research to identify the underlying causes of vascular inflammation associated with heart transplant rejection.
- Responsible for conducting gene analysis of patient biopsies, recording test results, and performing statistical analysis of the results.
- Responsible for preparing reports and presenting findings to the principal investigator and other researchers.

Gavin Cain

[redacted]

Gavin is an astute businessman with great insight, developed a chain of coffee shops across england and sold to a large conglomerate. His astute business acumen helped keep the overhead low by cutting on unnecessary labor and supply chain costs.

Cristal Tsen

[redacted]

An expert interior designer and construction manager and businesswoman. Oversaw and coordinated the renovation of dozens of multifamily apartment buildings, commercial buildings as well as medical condos. Did the interior design for all units from A to Z.

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	■ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH N/A	■ Retail/Community ☐ Hospital (# beds N/A) ☐ Internet ☐ Nuclear ☐ Other: N/A	■ Retail/Community ■ Dangerous drugs ■ Controlled substances DEA #: N/A ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other: N/A

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Health Works Pharmacy

Physical Address: 1440 N Eastern Ave

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address): 601 E Charleston Blvd Ste 100

City: Las Vegas State: NV Zip: 89104

Telephone: (650) 265-1193 Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: RalphMx@pm.me

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Yvonne Tamo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18959

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Yvonne Tamo	NV Pharmacist Registration #: 18959
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): N/A

Corporation Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): N/A

Corporation/Organization Name: Health Works Pharmacy

Mailing Address: 601 E Charleston Blvd Ste 100

City: Las Vegas State: NV Zip: 89104

Telephone: (650) 265-1193 Email: RalphMx@pm.me

Contact Person Name: Ralph Martinez

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Contact Person Name: N/A

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: N/A

Business Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Health Works Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Ralph Martinez

Print Name of Authorized Person

Ralph Martinez

Original signature of Authorized Person (copies or stamps not accepted)

11/19/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ralph Martinez hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Health Works Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Ralph Martinez
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of November, 2021

Notary Public

See Attached

California Jurat Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles } S.S.

Subscribed and sworn to (or affirmed) before me on this 19th day of November, (Month)

20 24, by Ralph Martinez

proved to me on the basis of satisfactory evidence to be the person(s) who appeared

before me.

Signature of Notary Public

NRO1 ANSON JACKSON NRO1
COMM. #2500698
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 11, 2028

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

The certificate is attached to a document titled/for the purpose of

containing _____ pages, and dated _____

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
○ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:

Page # _____ Entry # _____

Notary contact: _____

Other

☐ Affiant(s) Thumbprint(s) ☐ Describe: _____

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Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Yvonne Tamo Pharmacist Registration #: 18959

Pharmacy Name: Health Works Pharmacy

Initial each statement below to indicate you have read and agree with the following:

Y N I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

Y N I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

Y N I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

Y N I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

Y N I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
N/A	N/A	N/A	N/A

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A	N/A	N/A	N/A	N/A	N/A

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

11/18/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ralph Martinez

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Ralph Martinez

Original signature of Authorized Person (copies or stamps not accepted)

11/19/2024

Date

Board Use Only	Date Received: 11/21/24	Amount: $500-cc

Section 12: Provide all the applicable documents with your application based on your Business Type.

Non-publicly Traded

1. **List all Officers and Directors:**

President: Ralph Martinez

Secretary: Ralph Martinez

Treasurer: Ralph Martinez

Director: Ralph Martinez

2. **List the top four stockholders and their percent ownership**

Ralph Martinez, 100% Ownership.

3. **List all stockholders who hold 10% or more of the shares.**

Ralph Martinez, 100% Ownership.

As President, I authorize Yvonne Tamo to appear on behalf of the Corporation to the NV SBOP.

Ralph Martinez
Signature

Ralph Martinez
Printed Name

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of November, 2024

see Attached
Notary Public

California Jurat Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles S.S.

Subscribed and sworn to (or affirmed) before me on this 19th day of November, 20 24, by Ralph Martinez

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature of Notary Public

ANSON JACKSON
COMM. #2500698
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 11, 2028

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

The certificate is attached to a document titled/for the purpose of

containing _____ pages, and dated _____

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
○ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:

Page # _____ Entry # _____

Notary contact: _____

Other

☐ Affiant(s) Thumbprint(s) ☐ Describe: _____

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SECRETARY OF STATE

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Health Works Pharmacy** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/19/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/19/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202411195199267
You may verify this certificate online at https://www.nvsilvcrflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Health Works Pharmacy

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 1440 N Eastern Ave

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address): 601 E Charleston Blvd Ste 100

City: Las Vegas State: NV Zip: 89104

Telephone: (650) 265-1193 Website: N/A

Licensing Company Email: RalphMx@pm.me

Section 2: Personal Information

First: Yvonne Middle: N/A Last: Tamo

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☒ F ☐ X

Mailing Address[redacted]

City: Henderson State: NV Zip[redacted]

Telephone[redacted] Ema[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman Universtiy of Health Sciences		08/10-06/13	
Address	City	State	Zip
10920 S River Front Pkwy	South Jordan	UT	84094
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/99-08/20	
Address	City	State	Zip
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
BS Mathematics			
School Name		From - To (MM/YY – MM/YY)	
Sacramento State University		12/03-06/05	
Address	City	State	Zip
6000 J St.	Sacramento	CA	95841
Diploma/Degree obtained, if any			
N/A			
School Name		From - To (MM/YY – MM/YY)	
American River College		08/02-12/03	
Address	City	State	Zip
4700 College Oak Dr	Sacramento	CA	95841
Diploma/Degree obtained, if any			
N/A			
School Name		From - To (MM/YY – MM/YY	
East High School		03/97-06/99	
Address	City	State	Zip
840 South 1300 East	Salt Lake City	UT	84102
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/16-Present	[redacted]	Henderson	NV	[redacted]
01/15-10/16		Henderson	NV	
10/13-01/15		Bullhead City	AZ	
06/13-10/13		Turluck	CA	
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Goodwill Pharmacy, Inc.			05/24-Present
Business Address	**City**	**State**	**Zip**
2610 S. Jones Blvd. #3	Las Vegas	NV	89146
Phone	**Title**	**Number of Employed Hours**	
702-213-3102	Managing Pharmacist	600	

Description of Duties

Provide comprehensive patient care by processing and accurately dispensing prescription orders, counseling patients regarding health care and prescription medications needs.

Business Name			From - To (MM/YY – MM/YY)
Fort Mohave Indian Health Center Pharmacy			01/23-04/24
Business Address	**City**	**State**	**Zip**
1607 Plantation Rd	Mohave Valley	AZ	86440
Phone	**Title**	**Number of Employed Hours**	
928-346-4679	Pharmacist	2720	

Description of Duties

Review patient's medication profile for safety and effectiveness of drug therapy, review drug therapy for appropriateness relative to the patient's condition, processed, prepared, dispensed medication to patients, med counseling, etc.

Business Name			From - To (MM/YY – MM/YY)
Sam's Club Pharmacy			05/20-07/22
Business Address	**City**	**State**	**Zip**
8080 West Tropical Pkwy	Las Vegas	NV	89149
Phone	**Title**	**Number of Employed Hours**	
702-515-7214	Pharmacy Manager	3840	

Description of Duties

Provided comprehensive patient care to patients by accurately processing and dispensing prescription orders, immunization, improve quality and patient adherence via medication therapy management and counseling patients.

Business Name			From - To (MM/YY – MM/YY)
Sam's Club Pharmacy			04/15-05/20
Business Address	**City**	**State**	**Zip**
600 Hwy 95	Bullhead City	AZ	86429
Phone	**Title**	**Number of Employed Hours**	
928-754-3961	Pharmacy Manager	7680	

Description of Duties

Provided comprehensive patient care to patients by accurately processing and dispensing prescription orders, immunization, improve quality and patient adherence via medication therapy management and counseling patients.

Business Name			From - To (MM/YY – MM/YY)
Smith's Pharmacy			11/13-04/15
Business Address	**City**	**State**	**Zip**
1775 Lakeside Dr	Bullhead City	AZ	86442
Phone	**Title**	**Number of Employed Hours**	
928-763-8777	Pharmacist	3000	

Description of Duties

Review patient's medication profile for safety and effectiveness of drug therapy, review drug therapy for appropriateness relative to the patient's condition, processed, prepared, dispensed medication to patients, med counseling, etc.

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Yvonne Tamo, **certify that as the designated representative for**

Health Works Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YN I am at least 21 years of age;
3. YN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Yvonne Tamo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/18/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yvonne, Tamo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-18-24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Yvonne Tamo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-18-24

Date

Subscribed and Sworn to before me this 18th day of November, 2024

Notary Public Signature

FRANKIE VARELA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 01-18-27
(Seal) Certificate No: 12-9055-1

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Health Works Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 1440 N Eastern Ave

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address): 601 E Charleston Blvd Ste 100

City: Las Vegas State: NV Zip: 89104

Telephone: (650) 265-1193 Website: N/A

Licensing Company Email: RalphMx@pm.me

Section 2: Personal Information

First: Ralph Middle: N/A Last: Martinez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Mission Hills State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Los Angeles Valley College		02/2001 - 06/2001	
Address	**City**	**State**	**Zip**
5800 Fulton Ave	Valley Glen	CA	91401
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Pierce Community College		02/2000 - 12/2000	
Address	**City**	**State**	**Zip**
6201 Winnetka Ave	Woodland Hills	CA	91367
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Granada Hills High School		08/1993 - 06/1997	
Address	**City**	**State**	**Zip**
10535 Zelzah Ave	Granada Hills	CA	91344
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2001 - Present	[redacted]	Mission Hills	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
RM Consulting (Self Employed)			03/2020 - Present
Business Address	**City**	**State**	**Zip**
10035 Sepulveda Blvd. Unit C	Mission Hills	CA	91345
Phone	**Title**		
818-966-3941	President		

Description of Duties

Social media consulting that develops and implements tailored social media strategies for clients, optimizes profiles, tracks performance metrics, and provides guidance on content creation and advertising.

Business Name			From - To (MM/YY – MM/YY)
Creative Wood Works (Employed)			02/2015 - 09/2019
Business Address	**City**	**State**	**Zip**
621 Fitch Ave	Moorpark	CA	93021
Phone	**Title**		
805-523-0189	Sales and Social Media Marketing		

Description of Duties

Develop and execute social media strategies to promote the business and engage the target audience. Manage paid advertising campaigns, including budget allocation, audience targeting, and performance tracking.

Business Name			From - To (MM/YY – MM/YY)
Berman and Associates (Employed)			06/2012 - 12/2014
Business Address	**City**	**State**	**Zip**
9241 Reseda Blvd	Northridge	CA	91324
Phone	**Title**		
818-886-9590	Administrative Assistant		

Description of Duties

Manage schedules, appointments, and correspondence to ensure smooth daily operations. Handle client inquiries, maintain records, and organize files for easy access. Maintain office supplies and coordinate with vendors.

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		

Description of Duties

N/A

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		

Description of Duties

N/A

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ralph Martinez

Print Name (First, Last)

Ralph Martinez

Original Signature (electronic, copies or stamps not accepted)

11-19-24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ralph Martinez

Original Signature

11-19-24

Date

Subscribed and Sworn to before me this 19th day of November.

Notary Public Signature

See Attached

(Seal)

California Jurat Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles } S.S.

Subscribed and sworn to (or affirmed) before me on this 19th day of November,

20 24, by Ralph Martinez

proved to me on the basis of satisfactory evidence to be the person(s) who appeared

before me.

Signature of Notary Public

ANSON JACKSON
COMM. #2500698
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 11, 2028

NRO1 NRO1

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

The certificate is attached to a document titled/for the purpose of

containing _____ pages, and dated _____

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
○ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:

Page # _____ Entry # _____

Notary contact: _____

Other

☐ Affiant(s) Thumbprint(s) ☐ Describe: _____

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8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☒ Nuclear	DEA #: _____
	☐ Name Change* (if only Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH NU 02453		☐ Hospital
			☒ Other: Radiopharmaceuticals

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Las Vegas Radiopharmacy, Inc.

Physical Address: 1771 E. Flamingo Rd., #A121

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): NA

City: _____ State: _____ Zip: _____

Telephone: 702-476-8600 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 702-750-1367 Contact Email: licensing@rls.bio

Website: RLS.BIO

Nevada Business License # (if applicable) 2000086.325 (Currently under Advanced Isotopes of Nevada, LLC)

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Southwick, RPh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 11480

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Southwick, RPh	NV Pharmacist Registration #: 11480
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any):

Corporation/Organization Name: RLS (USA) Inc.

Mailing Address: 255 Primera Blvd., Suite #440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: jonathan.lucas@rls.bio

Contact Person Name: Jonathan Lucas

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the DIRECTOR, Q&R (title) for RLS (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

GLENN P. SULLIVAN

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/2/24

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Southwick Pharmacist Registration #: NV 11480

Pharmacy Name: Advanced Isotopes of Nevada

Initial each statement below to indicate you have read and agree with the following:

CS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	X	

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u> See Attach. A

Board Administrative Action:	State:	Date:	Case #:
Stipulation	NV	7-18-2014	14-017-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:
—	—	—	—	—	—

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Southwick

Original signature of Managing Pharmacist (copies or stamps not accepted)

7/1/2014

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

GLENN P. SULLIVAN

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/2/24

Date

Board Use Only	Date Received: 10/29/24	Amount: $500-cc

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. CHRISTOPHER GLEN SOUTHWICK, R.PH. Certificate of Registration No. 11480 ADVANCED ISOTOPES OF NEVADA Certificate of Registration No. PH02453 Respondents.	)	CASE NOS. 14-017-RPH-S 14-017-PH-S STIPULATION AND ORDER

S. Paul Edwards, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondents Christopher Southwick, Certificate of Registration No. 11480 and Advanced Isotopes of Nevada, Certificate of Registration PH02453, (collectively Respondents), appearing without counsel,

HEREBY STIPULATE AND AGREE THAT:

1. The Board has jurisdiction over this matter.

2. The Board properly served a Notice of Intended Action and Accusation (Accusation) on Respondents, and each of them, in connection with this action on or about March 12, 2014.

3. Respondents Advanced Isotopes of Nevada and Mr. Southwick filed a written Answer and Notice of Defense with the Board on or about March 26, 2014.

4. That Respondents were given the opportunity to seek the advice of counsel, and that they either obtained the advice of counsel, or voluntarily waived their right to seek the advice of counsel, prior to entering into this stipulation.

5. Respondents are aware of their right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal and any and all other rights which may be accorded to them pursuant to the Nevada Administrative Procedure Act (APA) and the Nevada Pharmacy Act (NPA).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of Paragraph 14 below, Respondents hereby freely and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by the APA and the NPA.

7. Respondents admit that evidence exists, and that Board Counsel could present such evidence at a hearing, to establish a factual basis for the violations alleged in the Accusation, to wit, that:

a. Respondent Southwick managed a pharmacy in which a pharmacy technician worked for twenty-one (21) days without a pharmacy technician license, in violation of Nevada Revised Statute (NRS) 639.220(1) and Nevada Administrative Code (NAC) 639.240(1), NRS 639.220(1) and 639.945(1)(i) and/or (j), and

b. Respondent Advanced Isotopes of Nevada owned and operated a pharmacy in which a pharmacy technician worked for twenty-one (21) days without a pharmacy technician license, in violation of NAC 639.240(1) and NAC 639.945(1) (i) and (2).

8. Respondents admit that the violations referenced in paragraph 7 above constitute grounds for discipline against them pursuant to NRS 639.255, NAC 639.945(2) and/or NAC 639.955.

9. The foregoing admissions are for the purposes of this proceeding only, and shall have no force or effect in any other case or proceeding before the Board.

10. Based upon the Accusation and the foregoing admissions, the Nevada State Board of Pharmacy and Respondents Advanced Isotopes of Nevada and Christopher Southwick stipulate to the following penalties:

a. Christopher Southwick, R.Ph. shall: (i) receive a public letter of reprimand from the Board Executive Secretary in connection with the violations set forth herein, (ii) complete a one hour continuing education (CE) course on the topic of Managing Pharmacist Responsibilities, or if such a course is not available, a course on ethics, in addition to the CE

credits he must ordinarily complete to maintain his license with the Board; (iii) pay a fine of $250.00; and (iv) pay an administrative fee of $45.00 to cover the Board's costs for processing the fingerprinting card for Mr. Southwick.

b. Advanced Isotopes of Nevada shall (i) pay a fine of $420.00, (ii) pay an administrative fee of $500.00 in connection with the Board's costs and expenses associated with this action; and (iii) to the extent possible, determine the cause of the violations set forth in the Accusation and stipulated to herein, and within a reasonable time not to exceed thirty (30) days after the effective date of the Board's Order, report to the Board the cause of the violation and the actions to prevent future similar reoccurrences.

11. Respondents shall pay the *fines* agreed to herein by cashier's check or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 431 W. Plumb Lane, Reno, NV 89509, within 30 days of the effective date of the Board's Order.

12. Respondents shall pay the *administrative fees* agreed to herein by cashier's check certified check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 431 W. Plumb Lane, Reno, NV 89509, within 90 days of the effective date of the Board's Order.

13. Board Counsel will present this stipulation to the Board Members for approval at the Board's regularly scheduled meeting on July 23, 2014, in Las Vegas, Nevada. Mr. Southwick, and a representative of Advanced Isotopes of Nevada will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this stipulation, even if Respondents and/or their counsel are not present at the meeting.

14. Any failure by Respondents to satisfy the obligations stated herein may result in additional discipline, up to and including suspension or revocation of license registration, until all terms have been complied with.

15. The Board and Respondents, and each of them, agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown, that might otherwise have existed on or before the effective date of the Board's Order in this matter.

I, as an authorized representative for Advanced Isotopes of Nevada, and Mr. Southwick, respectively, have fully considered the charges and allegations contained in the Notice of Intended Action and Accusation in this matter, and the terms of this Stipulation. I hereby freely and voluntarily agree to the terms set forth herein, and waive certain rights, as stated herein.

Signed this 18 day of July, 2014

Christopher Southwick, R.Ph.
Registration No. 11480

Signed this 18 day of July, 2014

Authorized Representative for
Advanced Isotopes of Nevada
Certificate of Registration No. PH02453

Agreed:

Signed this 22 day of July, 2014

S. Paul Edwards, Esq.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondents Christopher Southwick, R.Ph., Certificate of Registration #11480, and Advanced Isotopes of Nevada, Certificate of Registration #PH02453, and hereby orders that the terms of the foregoing Stipulation be made effective. This decision and order shall be effective upon execution.

7/23/2014
DATED

Kamlesh Gandhi, President
Nevada State Board of Pharmacy

ADVANCED
ISOTOPES OF NEVADA

Advanced Isotopes of Nevada
1090 E Desert Inn Rd #102
Las Vegas, NV 89109
January 29, 2014

S. Paul Edwards
General Counsel Nevada Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

Dear Sir,

This letter is in response to Case Number 14-017-RPH-S and 14-017-PH-S Stipulation and Order item #10 subsection b. (cause of violation and action to prevent future similar reoccurrences)

Venus started her rotation at Advanced Isotopes of Nevada LLC on August 19, 2013. One of the items covered during first day orientation is license verification (see attached Nuclear Pharmacy Rotation curriculum). I accept the original, or a copy of the original as proof of licensure. If the intern does not have it with them I will access the Nevada B.O.P website and print a copy for our records.

Venus presented a copy of an intern license which I looked at, thought to be her valid Nevada intern license, and posted it on our wall with our other licenses. No check of the Nevada B.O.P. website was performed.

Venus worked approximately 213 hours over the next 6 weeks. At the end of her rotation the copy of her intern license was either given back to her or put in the shred bin for destruction. Therefore I have no way to verify if this was an expired NV intern license, or an active CA intern license which also may have been presented.

On Jan 23, 2014 a representative from Roseman University called to inform me of Venus's expired intern license and a pending investigation by the B.O.P.

Going forward I will access the B.O.P website only for all licensure verification prior to the students/employee's start date and will keep copies. If active licensure cannot be verified, the intern/employee will not be allowed to start work and I will inform the B.O.P.

Sincerely,

Christopher G. Southwick R.Ph.
Pharmacy Manager
Advanced Isotopes of Nevada LLC

1090 E. Desert Inn Rd. Suite 102 Las Vegas NV 89109
Phone: 702-476-8600 Fax: 702-750-1376

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): PHNU02453- Currently Advanced Isotopes of Nevada, LLC.

Physical Address: 1771 E. Flamingo Rd. #A121

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): NA

City: State: Zip:

Telephone: 702476-8600 Toll Free # (NAC 639.708, NRS 639.23286):

Fax: Contact Email: Licensing@rls.bio

Website: RLS.BIO

Nevada Business License # (if applicable) 2000086.325- Currently Advanced Isotopes of Nevada, LLC.

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Southwick, RPh

Supervising/Managing Pharmacist NV Pharmacist Registration #: 11480

Name of Person with direct knowledge of compounding procedures: Christopher Southwick, RPh

Email of Person with direct knowledge of compounding procedures: [redacted]

Telephone of Person with direct knowledge of compounding procedures: [redacted]

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Tc^{99m} Radiopharmaceuticals (mibi, MDP, S Cell, DTPA, Mag3, Choletec, MAA, Myoview, Ceretec, PYP, HDP)

Ga^{67} "

In^{111} "

~~I^{131} Capsules~~ Other Co9

Tc^{99m} White Blood cell labeling

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

N/A

6. What laboratory performs this additional testing?

Name: _____

Address: N/A

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

Look for Particulate or cloudiness against a white & Black Background

8. How often do you perform glove fingertip and medial fill testing?

Annualy

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Educate & refest. Employee can not compound until refest is passed.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Initial: Observe Aseptic Hand Cleaning, Observe Disinfecting of compound Surfaces. Observe how appropriate Gown is Put on. Observe calculations when compounding Tc^{99m} kits. Have Employee read ASHP Compounding Sterile Preparations 3rd Ed. Show & Observe negative pressure Techniques. Observe & record Media Fill Testing. Observe & record Glove Fingertip Tests. Have Employee read USP 825.

Annual: Same as initial except Glove Fingertip is dynamic. Initial Fingertip is just Tests the ability to put gloves on & not contamination.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Daily: Clean Elution & Mixing vials & one step Disinfectant/Cleaner (PreEmpt+)
PEC & everything inside PEC & (PreEmpt+)
Sink & (PreEmpt+)
SRPA floor mop & (PreEmpt+)
SRPA work surfaces/shelves & (PreEmpt+)

Monthly: PEC, Bins, Shelves, Floors, walls, ceiling & (PreEmpt+)
PEC, Bins, Shelves, Floors, walls, ceiling & (Peridox) Sporicidal
Elution & Mixing vials & (Peridox) sporicidal

12. Who performs the sterile compounding process at your facility?

Chris Southwick RPh
Jeff Jorgenson Tech

13. Who is responsible and accountable for the sterile compounding process at your facility?

Chris Southwick

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All Radiopharmaceuticals are Shipped in Unit dose Shields inside a DOT Type A shipping container (Ammo can). Ammo cans are Blocked & Braced inside delivery vehicles.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds: N/A

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Southwick

Name of Person who Completed the Form

Pharmacy Manager

Title

Chris G. Southwick

Signature (copies or stamps not accepted)

7/1/24

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

MANAGEMENT SERVICES AND ASSET LICENSE AGREEMENT

MANAGEMENT SERVICES AND ASSET LICENSE AGREEMENT made as of the 11th day of October, 2024, by and between Advanced Isotopes of Nevada, LLC, a Nevada limited liability company ("Licensor"), and Las Vegas Radiopharmacy, Inc., a Delaware corporation (the "Company").

RECITALS

WHEREAS, the Company purchased the Assets, as defined in that certain Asset Purchase Agreement entered into by and between Manager and Company dated June 21, 2024 (the "Purchase Agreement"); and

WHEREAS, in order to operate its radiopharmaceutical business within the State of Nevada (the "Business"), the Company requires licenses issued by Nevada Board of Pharmacy and the Arizona Board of Pharmacy (the "Licenses"); and

WHEREAS, the parties have agreed to Close on the purchase of the Assets prior to the Company receiving the Licenses; and

WHEREAS, in order for Business to continue to operate, the Company desires to lease all of the Assets to Manager, and to engage Manager to continue to operate the day-to-day operations of the Business; and

WHEREAS; as part of the Purchase Agreement, Company has paid to Manager a Management Fee of TEN DOLLARS ($10.00), and other good and valuable consideration, the sufficiency of which is acknowledged by the Parties hereto.

NOW, THEREFORE, considering the above recitals and for good and valuable consideration, the parties agree as follows:

1. Definitions. All capitalized terms set forth in this Agreement and not defined herein shall have the meaning set forth in the Purchase Agreement.

2. Term. The term of this Agreement shall commence as of Closing (the "Commencement Date") and shall continue until the earlier of (i) six (6) months from the date this Agreement is executed and (ii) Company receives the Licenses (the "Term").

3. Services to be Rendered.

(a) Company hereby grants Manager a license to utilize the premises of the Business and the name "Advanced Isotopes of Nevada" or "AIN".

(b) Company hereby grants Manager an exclusive license to utilize all of the Assets and Manager agrees to license the use of the Assets from the Company. The use of the Assets is deemed reasonable and necessary by the parties for the proper and efficient operation of the Business. The Assets provided hereunder shall, at all times, be and remain the property of the Company.

4. Representations of the Company. The Company hereby makes the following representations, warranties and covenants to Manager, each of which is material and is being relied upon by Manager, and each of which shall be true as of the date hereof and shall continue during the term of this Agreement:

(a) Accuracy of Information. Any and all factual information furnished by the Company to Manager is true and accurate in all material respects and all information furnished by the Company to Manager in the future, will be true and accurate in all material respects as of the date on which such information is furnished.

(b) No Encumbrances. Title to the Assets shall remain with the Company.

(c) Duly Authorized. This Agreement has been duly authorized, executed and delivered by the Company and is binding upon it.

(d) Duly Organized. The Company is duly organized and in good standing under the laws of the State of Delaware as a corporation and authorized and qualified to do all things required of it under this Agreement.

(e) Capacity to Contract. The Company has the authority to fulfill the obligations required of it and them hereunder and nothing prohibits or restricts the right or ability of the Company to carry out the terms of this Agreement.

(f) Violations of Other Instruments. To the knowledge of the Company, neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby or thereby, violates (i) any agreement of the Company (ii) the certificate of organization or any governing documents of the Company, or (iii) any statute, ordinance, regulation, order, judgment or decree of any court or governmental agency or board, or conflicts with or will result in any breach or acceleration of any of the terms of or will constitute a default under or result in the termination of any contract or agreement to which the Company is a party or by which the Company is bound. No consents, approvals or authorizations of, or filings with, any governmental authority or any other person or entity are required to be obtained by the Company in connection with the execution and delivery of this Agreement.

5. Representations of the Manager. The Manager hereby makes the following representations, warranties and covenants to Company, each of which is material and is being relied upon by Company, and each of which shall be true as of the date hereof and shall continue during the term of this Agreement:

(a) Accuracy of Information. Any and all factual information furnished by the Manager to the Company is true and accurate in all material respects and all information furnished by the Manager to Company in the future, will be true and accurate in all material respects as of the date on which such information is furnished.

(b) Duly Authorized. This Agreement has been duly authorized, executed and delivered by the Manager and is binding upon it.

(c) Duly Organized. The Manager is duly organized and in good standing under the laws of the State of Nevada as a limited liability company and authorized and qualified to do all things required of it under this Agreement.

(d) Capacity to Contract. The Manager has the authority to fulfill the obligations required of it and them hereunder and nothing prohibits or restricts the right or ability of the Manager to carry out the terms of this Agreement.

(e) Violations of Other Instruments. To the knowledge of the Manager, neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby or thereby, violates (i) any agreement of the Manager, (ii) the certificate of organization or any governing documents of the Manager, or (iii) any statute, ordinance, regulation, order, judgment or decree of any court or governmental agency or board, or conflicts with or will result in any breach or acceleration of any of the terms of or will constitute a default under or result in the termination of any contract or agreement to which the Company is a party or by which the Manager is bound. No consents, approvals or authorizations of, or filings with, any governmental authority or any other person or entity are required to be obtained by the Manager connection with the execution and delivery of this Agreement.

6. Operation. In the performance of their respective obligations hereunder, the Company and the Manager shall comply with all applicable regulations and laws (including, without limitation, applicable Nevada and Arizona laws, regulations and rules) and shall use commercially reasonable efforts to ensure that the Business complies with the rules and regulations of all regulatory bodies, agencies or authorities having jurisdiction over them. Manager does not represent and warrant that this Agreement satisfies the requirement of the Nevada Board of Pharmacy or Arizona Board of Pharmacy and the Company assumes all risk that either of those entities may shut down the Business until such time as the Company obtains the appropriate Licenses.

7. Casualty. If any of the Assets are damaged or partially destroyed by fire or other casualty all risk of loss is with the Company unless the Manager was grossly negligent. The Company shall repair or replace, at Company's cost (or through the use of insurance proceeds) such damage.

8. Indemnity. The Company covenants and agrees that the Company will indemnify, defend and hold harmless Manager, and its members, managers, employees, successors and assigns for and against any loss, damage, liability or deficiency (including, without limitation, reasonable attorneys' fees and other costs and expenses incident to any suit, action, investigation or other proceeding)("Losses") arising out of or resulting from (i) any inaccuracy in any representation or the breach of any warranty made by the Company hereunder; (ii) any failure of the Company or its members or managers duly to perform or observe any material term, provision, covenant, agreement or condition hereunder on the part of the Company or such members or managers; and (iii) any claim, litigation or other action of any nature arising out of any act performed, transaction entered into or state of facts suffered to exist by virtue of the services performed by Manager under this Agreement, unless caused by the grossly negligent acts or omissions of the Manager, its agents and employees.

The Manager covenants and agrees that the Manager will indemnify, defend and hold harmless Company, and its members, managers, employees, successors and assigns for and

against any Losses arising out of or resulting from (i) any inaccuracy in any representation or the breach of any warranty made by the Manager hereunder; (ii) any failure of the Manager or its members or managers duly to perform or observe any material term, provision, covenant, agreement or condition hereunder on the part of the Manager or such members or managers; and (iii) any claim, litigation or other action of any nature arising out of any act performed, transaction entered into or state of facts suffered to exist by virtue of the services performed by Company under this Agreement, unless caused by the grossly negligent acts or omissions of the Company, its agents and employees.

9. Independent Contractor.

(a) This Agreement is by and between Manager and the Company and is not intended, and shall not be construed, to create an employment relationship, partnership or other such association as between the parties. Each party is an independent contractor of the other.

10. Default by the Company

(a) The occurrence of any one of the following shall constitute a default by the Company hereunder:

(i) if the Company attempts to or actually does remove, sell, transfer, encumber, subleases, sublicenses or part with possession of any of the Assets necessary to operate the Business outside of in the ordinary course of business;

(ii) if the Company is deemed to be in breach of any of the representations, warranties or covenants of this Agreement; or

(iii) if Company is deemed to be in breach of any of the representations, warranties or covenants of the Purchase Agreement.

(b) Upon a default by the Company, Manager shall have the right, after the expiration of a fifteen (15) day cure period, to immediately terminate this Agreement in addition to pursuing all rights and remedies it may have at law or in equity.

(c) The Company shall be entitled to written notice of any default and shall have fifteen (15) days from receipt of such notice to cure such default prior to the exercise of any remedy provided herein.

11. Default by Manager.

(a) The occurrence of any one of the following shall constitute a default by Manager hereunder.

(i) If Manager fails to observe or perform any of its obligations hereunder in any material respect and such failure continues uncured for a period of fifteen (15) days after written notice thereof to Manager from the Company or, if such failure cannot be cured within such fifteen (15) day period, the Manager has failed to commence to cure such failure within such fifteen (15) day period and diligently proceed to effect such cure;

(ii) If Manager: (A) makes an assignment for the benefit of creditors; (B) admits in writing its inability to pay its debt as they become due; (C) files a petition seeking reorganization and arrangement, readjustment or similar arrangement under the present or future statute, law or regulation, if any present or future; (D) files an answer admitting the material allegations of a petition filed against it and any such proceeding; or (E) consents to or acquiesces in the appointment of a trustee, receiver, or liquidator of all or any part of its assets or properties; or

(b) Upon a default by Manager, the Company shall have the right to immediately terminate this Agreement, in addition to pursuing all rights and remedies it may have at law or in equity.

12. Termination.

(a) This Agreement shall terminate upon the following events:

(i) the mutual written agreement of the parties;

(ii) as provided in Section 2;

(iii) as provided in Sections 10 and/or 11; or

(iv) in the event that any regulatory body declares that this Agreement requires that the Company have the Licenses.

(b) Surrender of Assets. Upon the termination of this Agreement, the Manager shall immediately relinquish control of the Assets to the Company.

13. Miscellaneous.

(a) Notices. Any notice or other communication required or which may be given hereunder shall be in writing and shall be delivered personally, sent by certified mail, postage prepaid, return receipt requested or by a nationally recognized overnight courier, and shall be deemed given when so delivered personally or by facsimile, or if mailed, five (5) days after the date of mailing as follows:

If to Manager:

Advanced Isotopes of Nevada, LLC
28 GENTILLY LACE AVENUE
HENDERSON, NV, 89002

***With a copy to, but which does not constitute notice*:**

Levine Garfinkel & Eckersley
Attn: Ira S. Levine, Esq.
1671 West Horizon Ridge Parkway,Suite 230
Henderson, Nevada 89012

Email: ilevine@lgealaw.com

If to the Company:

LAS VEGAS RADIOPHARMACY, Inc.
255 Primera Blvd
Suite 440
Lake Mary, FL 32746
Attention: Trey Bankson

***With a copy to, but which does not constitute notice*:**

Armbrecht Jackson LLP
Attn: Thomas P. Oldweiler
PO Box 290
Mobile, Alabama 36601
Email: tpo@ajlaw.com

or to such other address and to the attention of such other person(s) or officer(s) as either party may designate by written notice.

(b) Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of Nevada without regard to its conflicts of law principles. Venue for any action shall be the state courts located in Clark County, Nevada.

(c) Waiver of Jury Trial. Each party hereby waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation, directly or indirectly, arising out of or relating to this Agreement.

(d) Further Instruments. At any time and from time to time, each party shall, without further consideration and at its own expense, take such further actions and execute and deliver such further instruments as may be reasonably necessary to effectuate the purposes of this Agreement.

(e) Entire Agreement. This Agreement (including the exhibits hereto) contains the entire understanding between the parties hereto with respect to the transactions contemplated hereby and supersedes all prior agreements between them, written or oral.

(f) Severability. In the event that any term or provision of this Agreement is held to be illegal, invalid or unenforceable under any applicable law, rule or regulation, such term or provision shall be deemed severed from this Agreement and the remaining terms and provisions shall remain unaffected thereby provided the invalid term does not materially alter the basic purpose or intent of this Agreement.

(g) Assignment. Nothing in this Agreement shall permit assignment by either Party without the express prior written consent of the other Party.

(h) Waiver of Breach. No waiver of a breach of any provision of this Agreement shall be construed to be a waiver of any breach of any other provision of this Agreement or of any succeeding breach.

(i) Amendments. This Agreement shall not be changed or modified except by an instrument in writing executed by both parties hereto. Without limiting any other provision herein, in the event that rules, policies, directives and/or orders of the Nevada State Contractors Board, the City of Las Vegas or any other applicable federal, state, or local agency or third-party payor necessitate modifications or amendments to this Agreement, the parties hereto agree to so modify or amend this Agreement to conform with such rules, policies, directive and/or orders, provided they do not materially affect the duties and obligations of the parties hereunder.

(j) Counterparts. This Agreement may be executed in counterparts, each of which shall be considered an original and all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

MANAGER:

Advanced Isotopes of Nevada, LLC

By: _____
Name: Greg Spatafore
Title: CFO

COMPANY

Las Vegas Radiopharmacy, Inc.

By: _____
Name: Matt Molchan
Title: SVP, Business Development

SECRETARY OF STATE

STATE OF NEVADA

FOREIGN CORPORATION (80) QUALIFICATION

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **LAS VEGAS RADIOPHARMACY, INC.** did on **09/10/2024** file in this office its Qualification to do Business in this State and is now on file and of record in the office of the Nevada Secretary of State, and further, that said corporation is at the date of this Certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/10/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409104949793
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

LAS VEGAS RADIOPHARMACY, INC.

Nevada Business Identification # NV20243197775
Expiration Date: 09/30/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/10/2024.

Certificate Number: B202409104949794
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

Las Vegas Radiopharmacy, Inc. - Corporate Officers

Name	Title	Home Address/Phone	Email
Stephen Belcher	President /CEO	[redacted] Mobile AL [redacted]	[redacted]
Glenn Sullivarn	Director Regulatory Assurance	[redacted] Saint Paris OH [redacted]	[redacted]
Jonathan Lucas	Corporate Secretary	[redacted] Longwood FL [redacted]	[redacted]
Matt Molchan	Senior Vice President	[redacted] Atlanta GA [redacted]	[redacted]


RLS (USA) Inc.
255 Primera Blvd. Suite 440
Lake Mary, FL 32746
No single stockholders own greater than 10% of RLS (USA) Inc.
RLS (USA) Inc. is 100% Direct owner of
Las Vegas Radiopharmacy, Inc.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RLS (USA) Inc

Pharmacy/Wholesaler License # (if applicable) PW#402453 Advanced Isotopes of Nevada

Physical Address 1771 E Flamingo Rd ste A121

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address)

City State Zip

Telephone 702-476-8600 Website ~~UFA~~ RLS.BIO

Licensing Company Email licensing@rls.bio

Section 2: Personal Information

First Christopher Middle Glen Last Southwick

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	—	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
University of Utah college of Pharmacy	30 2000 E	Salt Lake City	UT	84112	8/1990 – 6/1993	B.S. RPh
University of Utah	201 Presidents Cir	Salt Lake City	UT	84112	8/86 – 6/1990	N/A
Alta High School	11055 S. 1000 E	Sandy	UT	84094	8/82 6/86	

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2016 – Pres	[redacted]	Las Vegas	NV	[redacted]
6/2001 to 8/2016	[redacted]	Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
Advanced Isotopes of Nevada		10/2008 to 7/2024
Business Address	**City**	**State / Zip**
1771 E Flamingo Rd Ste A124	Las Vegas	NV 89119
Phone	**Title**	**Number of Employed Hours**
702-476-8600	Pharmacy Manager	~33,000
Description of Duties		
Order & Compound Radiopharmacy Drugs, Manage Employees, Dispense compliance & stock of Federal Laws, Billing, Customer Service, Cleanliness ect.		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	X	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1985		UT	Salt Lake City	Salt Lake
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Unknown		Sandy Utah Metro Police		
Reason/Charge				
Vandalism				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Chris Southwick (minor)			—	
Name of Business/Industry/Entity				
—				

Provide explanation below:

Arrested for vandalism of a School Bus,

Chris G. Southwick

Original Signature (electronic, copies or stamps not accepted)

7/1/24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1985		UT	Salt Lake City	Salt Lake
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Unknown		Sandy, Ut Metro Police		
Reason/Charge				
Vandalism				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Chris Southwick			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Juvenile Record expunged @ 17yo

Original Signature (electronic, copies or stamps not accepted)

7/6/24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/2014	7/18/2014	NV	Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
14-017-RPh-S	Nevada Board of Pharmacy

Reason/Charge
Allowed an Intern to work without a valid Intern License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Christopher G Southwick	—

Name of Business/Industry/Entity
Advanced Isotopes of Nevada.

Provide explanation below:

Allowed Intern to work for 21 days & out on Intern License. Her License had Expired

Chris G. Southwick

Original Signature (electronic, copies or stamps not accepted)

7/1/24

Date

I, Christopher Southwick, **certify that as the designated representative for**

Advanced Isotopes of Nevada,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CS I am at least 21 years of age;
3. CS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Southwick

Print Name (First, Last)

Christopher Southwick

Original Signature (electronic, copies or stamps not accepted)

7/1/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Southwick

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/1/24

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, CHRISTOPHER GLEN SOUTHWICK, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/2/24

Date

Subscribed and Sworn to before me this 2 day of JULY 2024.

Notary Public Signature

CHARLES HARDING
Notary Public, State of Nevada
No. 20-6567-01
My Appt. Exp. Nov. 1, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Radiopharmacy Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PHNU 02453- currently Advanced Isotopes

Physical Address: 1771 E. Flamingo Rd., #A121

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): NA

City: State: Zip:

Telephone: 702-476-8600 Website: RLS.BIO

Licensing Company Email: licensing@rls.bio

Section 2: Personal Information

First: Stephen Middle: Andrew Last: Belcher

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Lake Mary State: FL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of South Alabama		09/82-06/88	
Address	City	State	Zip
307 N. University Blvd.	Mobile	AL	36688
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
McGill-Toolen High		09/78-06/82	
Address	City	State	Zip
1501 Old Shell Rd.	Mobile	AL	36604
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/24-Present	[redacted]	Miramar Beach	FL	[redacted]
07/20-06/24		Mobile	AL	
07/06-07/20		Dauphin Island	AL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
RLS (USA) Inc.			9/22-Present
Business Address	**City**	**State**	**Zip**
255 Primera Blvd. Suite 440	Lake Mary	FL	32746
Phone	**Title**		
813-285-3065	CEO		

Description of Duties

Management of RLS (USA) Inc.

Business Name			From - To (MM/YY – MM/YY)
KANO Performancw			4/19- Present
Business Address	**City**	**State**	**Zip**
182 St. Francis Street	Mobile	AL	36602
Phone	**Title**		
251-616-2033	President		

Description of Duties

Overseeing budgets, staff, and executives and evaluating the success of the company.

Business Name			From - To (MM/YY – MM/YY)
Medical Sales and Management Strategies, LLC			7/14-Present
Business Address	**City**	**State**	**Zip**
9425 Private Rd., 166	Theodore	AL	36582
Phone	**Title**		
	Chairman of the Board		

Description of Duties

Lead the board, focus on strategic matters, oversee business and setting high governance standards. Play pivotal role in fostering the effectiveness of the board and individual directors.

Business Name			From - To (MM/YY – MM/YY)
PermaFix Medical S.A.			2/18-2/19
Business Address	**City**	**State**	**Zip**
Skarbowcow 23a, 53-025	Wroclaw Poland		
Phone	**Title**		
48 71 735 7005	CEO		

Description of Duties

Management of company

Business Name			From - To (MM/YY – MM/YY)
Global Pet Imaging			7/14-11/15
Business Address	**City**	**State**	**Zip**
182 St. Francis Street	Mobile	AL	36602
Phone	**Title**		
	CEO		

Description of Duties

Management of company

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Triad Isotopes			1/07-7/14
Business Address	City	State	Zip
182 Saint Francis Street	Mobile	AL	36602
Phone	Title		
	SVP		
Description of Duties			
Over all sales efforts			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

STEPHEN BELCHER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JULY 1, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of ALABAMA, ss. County of MOBILE

I, STEPHEN A. BELCHER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7.1 2024

Date

Subscribed and Sworn to before me this 1ST day of July, 2024

Notary Public Signature

THOMAS P. OLDWEILER NOTARY PUBLIC (Seal) ALABAMA STATE AT LARGE

M.C.E. 3.29.26

8E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	■ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	■ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	■ Retail/Community ■ Dangerous drugs ■ Controlled substances DEA #: N/A ■ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Lumis Pharmacy LLC

Physical Address: 10410 S Decatur Blvd, Suite A-102

City: Las Vegas State: NV Zip: 89141

Mailing Address (if different from physical address): 10956 Royal Highlands St

City: Las Vegas State: NV Zip: 89141

Telephone: 4054360220 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: asangaleslie@gmail.com

Website: _____

Nevada Business License # (if applicable) NV20243186499

Supervising/Managing Pharmacist Name (NRS 639.220): Leslie Asanga

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19612

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Leslie Asanga	NV Pharmacist Registration #: 19612
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Leslie Asanga

Business Name: Lumis Pharmacy LLC

Business Address: 10410 S Decatur Blvd, Suite A-102

City: Las Vegas State: NV Zip: 89141

Telephone: 4054360220 Email: asangaleslie@gmail.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Lumis Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Leslie Asanga

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

08/16/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Leslie Asanga hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Lumis Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

State of Nevada
County of Clark
SUBSCRIBED AND SWORN TO
Before me, a notary public this 16 day of August, 20 24
by Leslie Asanga

B Genter
Notary Public

B. Genter
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 23-0229-01
My Appt. Expires August 10, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Leslie Asanga Pharmacist Registration #: 19612

Pharmacy Name: Lumis Pharmacy

Initial each statement below to indicate you have read and agree with the following:

LA I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

LA I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

LA I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

LA I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

LA I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

08/16/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leslie Asanga

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

08/16/2024

Date

Board Use Only	Date Received: 8/19/24	Amount: $500-CL

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Lumis Pharmacy LLC** did, on 08/21/2024, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/21/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202408214896286
You may verify this certificate
online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Lumis Pharmacy LLC

Nevada Business Identification # NV20243186499
Expiration Date: 08/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/21/2024.

Certificate Number: B202408214896287
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Lumis Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 19612

Physical Address: 300 S 4th St, Ste 180

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address): 300 S 4th St, Ste 180

City: Las Vegas State: NV Zip: 89101

Telephone: 4054360220 Website:

Licensing Company Email: asangaleslie@gmail.com

Section 2: Personal Information

First: Leslie Middle: Last: Asanga

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Yale University			07/2019 - 05/2020
Address	**City**	**State**	**Zip**
100 College St	New Haven	CT	06520
Diploma/Degree obtained, if any			
MPH			

School Name			From - To (MM/YY – MM/YY)
Roseman University			07/2014 - 06/2017
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD/MBA			

School Name			From - To (MM/YY – MM/YY)
Tarrant County College			10/2012 - 07/2014
Address	**City**	**State**	**Zip**
828 W Harwood Rd,	Hurst	TX	76052
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
Oklahoma State University Oklahoma City			01/2011-10/2012
Address	**City**	**State**	**Zip**
900 N Portland Ave	Oklahoma City	OK	73107
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY
Government Bilingual High School			09/1999 - 06/2002
Address	**City**	**State**	**Zip**
Santa Subdivision	Santa	NA	NA
Diploma/Degree obtained, if any			
GCE Advanced Level			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2021 - Present	[redacted]	Las Vegas	NV	[redacted]
06/2016 - 07/2021		Henderson	NV	
06/2015 - 06/2016		Henderson	NV	
07/2014 - 06/2015		Henderson	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Pills2Me Inc.			03/2020 - 10/2024
Business Address	**City**	**State**	**Zip**
300 S 4th St	Las Vegas	NV	89101
Phone	**Title**		
7252157343	CEO		

Description of Duties

Overseeing all aspects of the venture.

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			10/2017 - 04/2020
Business Address	**City**	**State**	**Zip**
2011 E Lake Mead Blvd	Las Vegas	NV	89030
Phone	**Title**		
7026491991	Pharmacist		

Description of Duties

Participating in and supervising all activities in the pharmacy including, but not limited to, data entry, data entry verification, prescription dispensing, patient counseling, immunization, inventory management, pharmacy technician

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			10/2014 - 03/2016
Business Address	**City**	**State**	**Zip**
3808 E Tropicana Ave	Las Vegas	NV	89121
Phone	**Title**		
7025470830	Pharmacy Intern		

Description of Duties

Data entry, filling prescriptions, patient counseling, immunization, inventory management, checking out patients at point of sale, and assisting in whatever was required by the pharmacist on duty.

Business Name			From - To (MM/YY – MM/YY)
Walmart Pharmacy			06/2013 - 07/2014
Business Address	**City**	**State**	**Zip**
8401 Anderson Blvd	Fort Worth	TX	76120
Phone	**Title**		
8172769021	Pharmacy Technician		

Description of Duties

Data entry, filling prescriptions, inventory management, checking out patients at point of sale, and assisting in whatever was required by the pharmacist on duty.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leslie Asanga

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/01/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Leslie Asanga, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/01/2024

Date

Subscribed and Sworn to before me this 10 day of OCT 2024

Notary Public Signature

STEVEN PETRACK
Notary Public, State of Nevada
Appointment No. 11-5505-1
My Appt. Expires May 27, 2026

(Seal)

8F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FQ 11 37810
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04405		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: QHR Pharmacy # 3 LLC

Physical Address: 3375 E Russell Rd # 1G

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): Same as the above.

City: _____ State: _____ Zip: _____

Telephone: 702-331-3414 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-331-3413 Contact Email: Medtrust89120@gmail.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Emily Lin Taing

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24367

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Emily Lin Taing	NV Pharmacist Registration #: 24367
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Mahmoud Noveldeen

Business Name: QHR Pharmacy 3

Business Address: 3375 E Russell Rd # 1G

City: Las Vegas State: NV Zip: 89120

Telephone: 702-331-3414 Email: Medtrust89120@gmail.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for QHR Pharmacy 3 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Emily Tang

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/17/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Emily Tang hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for QHR3 Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18th day of October, 20 24

Notary Public

YUVRAJ SINGH
Notary Public, State of Nevada
No. 23-5114-01
My Appt. Exp. April 10, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Emily Lin Taing Pharmacist Registration #: 24367

Pharmacy Name: QHR Pharmacy 3

Initial each statement below to indicate you have read and agree with the following:

ET I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

ET I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

ET I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

ET I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

ET I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emily Lin Taing 10/17/24

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emily Taing

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/17/24

Date

Board Use Only	Date Received: 10/21/24	Amount: $500 CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler QHR 3 Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH 04465

Physical Address 3375 E Russell Rd # 1G

City Las Vegas State NV Zip 89120

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 702-331-3414 Website N/A

Licensing Company Email Medtrust 89120@gmail.com

Section 2: Personal Information

First Emily Middle Un Last Tang

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/21 - 05/24	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Pharm. D			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Las Vegas		08/2017 - 05/2021	
Address	**City**	**State**	**Zip**
4505 S. Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
Bachelor of Science Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/07 - now	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
AHR Pharmacy		10/17/24 - Present
Business Address	**City**	**State / Zip**
3375 E Russell Rd #16	Las Vegas	NV 89120
Phone	**Title**	**Number of Employed Hours**
702-331-3414	PIC	0

Description of Duties
- Verify rx
- Supervise staff
- manage inventory
- resolve 3rd party
- Contact prescriber

Business Name		From - To (MM/YY – MM/YY)
North Vista Hospital		01/22 - 05/24
Business Address	**City**	**State / Zip**
1409 E. Lake Mead Blvd	Las Vegas	NV 89030
Phone	**Title**	**Number of Employed Hours**
702-649-7711	Pharmacy intern	2,000

Description of Duties
- Reconstitute
- delivermeds
- Record keeping
- abx monitoring
- Packing

Business Name		From - To (MM/YY – MM/YY)
CVS Pharmacy		01/20 - 09/23
Business Address	**City**	**State / Zip**
2430 Bicentennial Pkwy	Henderson	NV 89044
Phone	**Title**	**Number of Employed Hours**
702-260-8414	Pharmacy tech / intern	7,500

Description of Duties
- fill / type scripts
- counseling
- License administration
- resolve 3rd party issues

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Emily Tunny, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. EG I am at least 21 years of age;
3. EG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. EG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. EG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. EG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. EG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Emily Tunny

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/17/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emily Tang
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/17/24
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Emily Tang, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/19/24
Date

Subscribed and sworn to before me this 18th day of October, 2024

Notary Public Signature

YUVRAJ SINGH
Notary Public, State of Nevada
No. 23-5114-01
My Appt. Exp. April 10, 2027
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler QHR 3 Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) PH04405

Physical Address 3375 E Russell Rd # 1G

City Las Vegas State NV Zip 89120

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 702-331-3414 Website N/A

Licensing Company Email Medtrust89120@gmail.com

Section 2: Personal Information

First Emily Middle Lin Last Tsing

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/2021 - 05/2024	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Las Vegas		08/2017 - 05/2021	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
Bachelors of Science Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2007 - Now	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
911R Pharmacy		10/17/24 – present	
Business Address	**City**	**State**	**Zip**
3375 E Russell Rd #16	Las Vegas	NV	89120
Phone	**Title**		
702-331-3414	PIC		

Description of Duties
- Verify Rx - Supervise techs/intern - contact prescribers
- manage inventory - resolve 3rd party issues

Business Name		From - To (MM/YY – MM/YY)	
North Vista Hospital		01/2023 - 05/2024	
Business Address	**City**	**State**	**Zip**
1409 E Lake Mead Blvd	Las Vegas	NV	89030
Phone	**Title**		
702-649-7711	Pharmacy intern		

Description of Duties
- restock ADC - record keeping - nursing/full audits
- deliver meds - clinic monitoring

Business Name		From - To (MM/YY – MM/YY)	
CVS Pharmacy		01/20 - 09/23	
Business Address	**City**	**State**	**Zip**
2830 Bicentennial Pkwy	Henderson	NV	89044
Phone	**Title**		
702-260-8414	Pharmacy tech/intern		

Description of Duties
- fill/type scripts - Immunizations
- counsel patients - resolve 3rd party issues

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emily Tsang
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/17/24
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Emily Tsang, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/18/24
Date

Subscribed and Sworn to before me this 18th day of October, 2024

Notary Public Signature

YUVRAJ SINGH
Notary Public, State of Nevada
No. 23-5114-01
My Appt. Exp. April 10, 2027
(Seal)

1:7 18/625

QHR PHARMACY 3, LLC
3375 E RUSSELL RD # 1G
LAS VEGAS, NV 89120-3472

1000312 2/00814-1/1.0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FQ1137810	04-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	01-28-2022

QHR PHARMACY 3, LLC
3375 E RUSSELL RD # 1G
LAS VEGAS, NV 89120-3472

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FQ1137810	04-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	01-28-2022

QHR PHARMACY 3, LLC
3375 E RUSSELL RD # 1G
LAS VEGAS, NV 89120-3472

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler QHR Pharmacy 3, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) PH04405

Physical Address 3375 E Russel Rd. #1G,

City Las Vegas State NV Zip 89120

Mailing Address (if different from physical address) NA

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email Medtrust89120@gmail.com

Section 2: Personal Information

First Mahmoud Middle M Last Noureldeen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Addres [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University Of the people		09/21 - 01/24	
Address	**City**	**State**	**Zip**
595 E Colorado Blvd Suite 623	Pasadena	CA	91101
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Al-Azhar University		09/02-06/06	
Address	**City**	**State**	**Zip**
Al Mokhaym Al Daem	Nasr City		
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
al siddiq high school		10/99-06/02	
Address	**City**	**State**	**Zip**
Gamal Al Din Al Afghani	Giza		
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/24 -current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/23 -09/24		Las Vegas	NV	
From - To (MM/YY -- MM/YY)		City	State	
04/15 - 09/23		Allen	TX	
From - To (MM/YY – MM/YY)		City	State	
03/11 - 03/15		Hicksville	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY -- MM/YY)	Address	City	State	Zip
From - To (MM/YY -- MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY -- MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
QHR pharmacy 3, LLC			10/24 - Current
Business Address	**City**	**State**	**Zip**
3375 E Russel Rd. #1G	Las Vegas	NV	89120
Phone	**Title**		
702 331 3414	Clerk		

Description of Duties

Supports the pharmacy team by assisting customers with locating products and handling general inquiries, managing transactions and insurance processing, and organizing inventory.

Business Name			From - To (MM/YY – MM/YY)
United Nations World Food Programme			7/20-09/24
Business Address	**City**	**State**	**Zip**
733 3rd Ave #23, New York	New York	NY	10017
Phone	**Title**		
646-556-6901	IT Operations		

Description of Duties

Monitored and maintained systems to ensure stability and resolved issues remotely. Provided technical support, addressing software, hardware, and connectivity needs, and managed network security, implementing VPNs and firewall

Business Name			From - To (MM/YY – MM/YY)
Paloalto networks			02/15-06/20
Business Address	**City**	**State**	**Zip**
3901 Dallas Pkwy	Plano	TX	75093
Phone	**Title**		
972-424-6307	Technical Support Engineer		

Description of Duties

Provided troubleshooting, configured systems, diagnosed network issues, and maintained clear documentation to track solutions and improve reliability.

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			02/13-10/14
Business Address	**City**	**State**	**Zip**
210 S Broadway	Hicksville	NY	11801
Phone	**Title**		
516-433-2711	Clerk & Pharmacy Tech		

Description of Duties

Supports the pharmacy team by assisting customers with locating products and handling general inquiries, managing transactions and insurance processing, and organizing inventory.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MAHMOUD NOURELDEEN

Print Name (First, Last)

M. Nour

Original Signature (electronic, copies or stamps not accepted)

11/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MAHMOUD NOURELDEEN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

M. Nour

Original Signature

11/14/2024

Date

Subscribed and Sworn to before me this 14 day of NOVEMBER 2024

Notary Public Signature

SETH GUTIERREZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 23-1983-01
MY APPT. EXPIRES MARCH 23, 2027

(Seal)

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 02496	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Allergychoices Pharmacy

Physical Address: 2731 National Drive

City: Onalaska State: WI Zip: 54650

Mailing Address (if different from physical address): N/A - same as physical address

City: _____ State: _____ Zip: _____

Telephone: (608) 793-1580 Toll Free # (NAC 639.708, NRS 639.23286): (866) 793-1680

Fax: (608) 793-1571 Contact Email: msprosty@allergychoices.com

Website: www.allergychoices.com

Nevada Business License # (if applicable) PH02496

Supervising/Managing Pharmacist Name (NRS 639.220): Maci Sprosty

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21932

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Maci Sprosty	NV Pharmacist Registration #: 21932
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Noon & Freeman Co.

Corporation/Organization Name: Allergychoices, LLC

Mailing Address: 2731 National Drive

City: Onalaska State: WI Zip: 54650

Telephone: (608) 793-1580 Email: msprosty@allergychoices.com

Contact Person Name: Maci Sprosty

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Executive Officer (title) for Allergychoices Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Eugene Kakaulin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/26/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Eugene Kakaulin hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Executive Officer (title) for Allergychoices Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26 day of February, 2024

Notary Public

ANNA KROTENKO
Notary Public - State of New York
NO. 01KR0009158
Qualified in Kings County
My Commission Expires Jun 6, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eugene Kakaulin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

02/26/2025

Date

Board Use Only	Date Received: 3/4/25	Amount: $500 - check 417632

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALLERGYCHOICES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF JUNE, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

4056705 8300

SR# 20242995694

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203804878

Date: 06-26-24

LicensE (/s/)

Home

Request Support



DSPS Site Guest User

Third Party Document Upload Application Status Lookup LEAP Login

Provider Login Performance Data File a Complaint

Orders and Disciplinary Actions License Lookup

Credential/License Summary for 9342 - 42 As of December 10, 2024 8:31:20 AM

Name : ALLERGYCHOICES PHARMACY

Credential/License Number : 9342 - 42

Professions : Pharmacy (In-State)

Location : ONALASKA, Wisconsin - 54650

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2015-08-17

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 9342 - 42

No Orders Found

Relationships for 9342 - 42

Individual

NAME
Michael B Kachel

LICENSE NO 10748 - 40 (/s/licenseView?id=0cE3d0000000mwqEAA)

LOCATION Onalaska, Wisconsin

TYPE Managing Person

START DATE 2024-05-31

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Allergychoices Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH02496

Physical Address: 2731 National Drive

City: Onalaska State: WI Zip: 54650

Mailing Address (if different from physical address): N/A - same as physical address

City: State: Zip:

Telephone: (608) 793-1580 Website: www.allergychoices.com

Licensing Company Email: msprosty@allergychoices.com

Section 2: Personal Information

First: Maci Middle: Marie Last: Sprosty

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: La Crosse State: WI Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
Concordia University Wisconsin	08/15-05/19		
Address	**City**	**State**	**Zip**
12800 N Lake Shore Dr	Mequon	WI	53097
Diploma/Degree obtained, if any			
PharmD			

School Name	From - To (MM/YY – MM/YY)		
University of Wisconsin - Stevens Point	08/11-05/15		
Address	**City**	**State**	**Zip**
2100 Main St	Stevens Point	WI	54481
Diploma/Degree obtained, if any			
Bachelors			

School Name	From - To (MM/YY – MM/YY)		
North Crawford	08/07-05/11		
Address	**City**	**State**	**Zip**
47050 County Road X	Soldiers Grove	WI	54655
Diploma/Degree obtained, if any			
High School Diploma			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/21- current	[redacted]	La Crosse	WI	[redacted]
10/18-5/21		La Crosse	WI	
08/18-10/18		Gays Mills	WI	
08/15-08/18		Grafton	WI	
08/14-08/15		Stevens Point	WI	
02/14-08/14		Gays Mills	WI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Allergychoices Pharmacy			05/21-current	
Business Address		City	State	Zip
2731 National Dr		Onalaska	WI	54650
Phone	Title		Number of Employed Hours	
608-793-1580	Pharmacist		5,600	
Description of Duties				
Work 40 hours per week. Dispense prescription medication and provide information to patients about the drugs, safety, and their use. Advise physicians and other healthcare workers on the selection, dosage, interactions, and side effects.				

Business Name			From - To (MM/YY – MM/YY)	
Vernon Memorial Pharmacy			12/19-08/22	
Business Address		City	State	Zip
407 S Main St #104		Viroqua	WI	54665
Phone	Title		Number of Employed Hours	
608-637-4717	Pharmacist		<200	
Description of Duties				
Occasional pharmacist - only worked shifts when needed. Same duties as above.				

Business Name			From - To (MM/YY – MM/YY)	
Walgreen's Pharmacy			05/19-05/21	
Business Address		City	State	Zip
900 West Ave S		La Crosse	WI	54601
Phone	Title		Number of Employed Hours	
608-796-2058	Pharmacist		3,328	
Description of Duties				
Worked minimum 32 hours per week. Same duties as above.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Maci Sprosty, **certify that as the designated representative for**

Allergychoices Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MS I am at least 21 years of age;
3. MS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Maci Sprosty

Print Name (First, Last)

Maci M

Original Signature (electronic, copies or stamps not accepted)

2/22/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maci Sprosty

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

2/22/24

Date

Please have this section completed in the presence of a Notary Public.

State of Wisconsin, ss. County of La Crosse

I, Maci Sprosty, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/23/2024

Date

Subscribed and Sworn to before me this 23rd day of February, 2024

Notary Public Signature

My commission expires 02/21/2028

(Seal)

WISCONSIN DEPARTMENT OF
SAFETY AND PROFESSIONAL SERVICES

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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	**FINAL DECISION AND ORDER**
ALLERGYCHOICES, INC., d/b/a ALLERGYCHOICES PHARMACY, RESPONDENT.	:	
	:	ORDER 0002288

Division of Legal Services and Compliance[1] Case No. 11 PHM 71

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Allergychoices, Inc.
2800 National Drive, Suite 100
Onalaska, WI 54650

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent Allergychoices, Inc., d/b/a Allergychoices Pharmacy, is licensed in the State of Wisconsin as a pharmacy, having license number 42-8984, first issued on December 14, 2009, and current through May 31, 2014. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 2800 National Drive, Suite 100, Onalaska, WI 54650. Respondent's pharmacy is engaged exclusively in the compounding of liquid sublingual immunotherapy (SLIT) preparations.

[1] The Division of Legal Services and Compliance was formerly known as the Division of Enforcement.

2. The typical practice of the pharmacy has been that, upon receipt of a prescription for an individual patient, a 90 day supply of liquid medication is prepared with glycerin as a diluent/preservative, and dispensed in a bottle with a metered pump. The bottle is labeled for the patient, and shipped via Postal Service priority mail. In over 80% of cases, the initial medication is shipped to the prescriber's office, for the purpose of allowing the prescriber to observe the initial administration to the patient.

3. Respondent does not have a variance which would permit delivery of a prescription to a place other than the patient's residence.

4. In the majority of cases, the prescriber is billed for the medication by the pharmacy, with the expectation that the prescriber will pay the pharmacy directly, and then collect reimbursement from the patient.

5. In all other cases, the patient is billed by the pharmacy, and pays the pharmacy directly.

6. Respondent assures the Board that the practices described in paragraphs 3 and 4, above, will cease immediately.

7. In April 2007, Respondent caused to be prepared a piece of literature entitled "Answers to Common Questions about SLIT for Medical Staff" which is listed as "updated 4/07." Under a section entitled "Business Issues" was the following:

> Q: Is it legal to re-sell the drops we have formulated by your pharmacy?
> A: You should check your state regulations regarding re-selling of prescriptions. We are not aware of specific statutes that prohibit physicians from marking up a compounded prescription.

8. The Board finds that compounding for resale constitutes manufacturing under federal law, an activity for which Respondent was not licensed in Wisconsin, nor registered with the FDA. Respondent's position is that it was not functioning as a manufacturer. Rather, Respondent contends that it was dispensing patient-specific prescriptions to the patient via the physician, who functioned as an agent of the patient by accepting and paying for the prescription on the patient's behalf. The Board finds that all financial arrangements and transactions must be directly and exclusively between the patient and the pharmacy.

9. Respondent's managing pharmacist has represented to the Board that he was unaware of the existence of this piece of literature, which was prepared by persons not under his supervision. The Board finds that this constitutes failing to place the pharmacy under the control of a managing pharmacist, as required by Wis. Stat. § 450.09(1)(a).

10. Respondent does not have records of the number of pieces of literature, as described in paragraph 7, above, which were distributed to potential prescribers. Respondent represents to the Board that in January, 2008, Respondent revised the piece of literature referred to, above, and replaced it with a version stating the following:

> Q: Is it legal to re-sell the drops we have formulated by your pharmacy?
> A: No – a patient prescription cannot be marked up by a third party.

11. Presently, Respondent uses the following language in the successor to this particular piece of literature:

> Q: Can I mark up the cost of the prescription?
> A: No, Allergychoices is a retail pharmacy that prepares patient-named prescriptions, and like any other retail prescription, patient prescription charges must reflect actual retail pricing. Refer to your practice is standard pricing policy for any additional charges for staff time, office overhead and professional services that accompany, but are separate from, charges for prescriptions.

12. On rare occasion, a patient is thought to be intolerant to glycerin. On such occasions, Respondent's practice has been to compound the prescription using sterile water as a primary diluent, although some glycerin accompanies the active ingredient. Respondent does not have a protocol for assuring the safe delivery of such a prescription, nor is it given an appropriate expiration date (two weeks). Literature furnished by Respondent supporting glycerin as an effective preservative in lower concentrations did not, in fact, support Respondent's practice in all cases.

13. Respondent's labeling does not include the quantity or concentration of each active ingredient, in a manner which another health care practitioner could readily understand.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in Finding of Fact 3, Respondent violated Wis. Admin. Code § Phar 7.01(1)(e), in that a prescription may be delivered only to a patient's residence unless the Board has granted a variance permitting delivery elsewhere.

3. By the conduct described in Findings of Fact 4 and 7, Respondent violated Wis. Admin. Code § Phar 10.03(1), in that the pharmacy's financial arrangements and transactions were not always directly and exclusively between the patient and the pharmacy.

4. By the conduct described in Finding of Fact 9, Respondent violated Wis. Stat. §§ 450.10(1)(a)2. and 450.09(1)(a), in that every pharmacy shall be under the control of the managing pharmacist, and the managing pharmacist shall be responsible for the professional operations of the pharmacy.

5. By the conduct described in Finding of Fact 12, Respondent violated Wis. Admin. Code § Phar 10.03(2).

6. By the conduct described in Finding of Fact 13, Respondent violated Wis. Admin. Code § Phar 10.03(16).

7. As a result of the above violation, Allergychoices, Inc., is subject to discipline pursuant to Wis. Stat. § 450.10(1).

ORDER

1. The attached Stipulation is accepted.

2. Allergychoices, Inc., is REPRIMANDED.

3. Allergychoices, Inc., shall FORFEIT $1,000, to be paid within 30 days of this Order.

4. Allergychoices, Inc., shall label all compounded prescriptions in compliance with USP 795.

5. Within 30 days from the date of this Order, Respondent shall pay the COSTS of this matter in the amount of $3,500.

6. Payment of forfeiture and costs shall be made payable to the Wisconsin Department of Safety and Professional Services and sent to the Department Monitor at the address below:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 8935, Madison, WI 53708-8935
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

7. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of the forfeiture or costs as ordered, Respondent's license (42-8984) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of the forfeiture and costs.

8. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ February 13, 2013
A Member of the Board Date

akt

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

-Pharmacy-

Date: 8/1/2013

Dear Respondent,

You have been ordered to pay a fine to the Division of Occupational and Professional Licensing:

Your fine of $500.00 **is due** November 1, 2013*

Your case number is DOPL- 2013-313 Allergychoices

*If you are unable to pay the fine as indicated in your Order or your Order indicates other arrangements, you must contact me or my co-worker Carol Inglesby within ten (10) days from the date of this letter. No special considerations will be granted for failure to contact us within the ten (10) day limit.

Make check(s) payable to DOPL and remit to:

DOPL
Attn: Disciplinary Files
P O Box 146741
Salt Lake City UT 84114-6741

Or you may pay with a Visa/Mastercard/American Express. Please mail your card number and expiration date to the above address or call (801)530-6088 and leave the information. Ms. Inglesby's phone number is (801)530-6626.

Please be sure to include your case number on any correspondence you send us.

Thank you,

Kim Lesh

Kim Lesh
Administrative Secretary

Discp/Fine letter 03/06

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby waives all administrative and judicial review as set forth in §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-46b-12 through R151-46b-15. Respondent and the Division hereby express their intent that that matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's licenses, to other persons and entities.

and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent agrees that the time period for completion of that term or condition shall be set by the Board. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

BY: _____
RICHARD J. OBORN
Bureau Manager

DATE: 7/29/13

RESPONDENT

BY: _____
JEFFREY KESSLER
President
Allergychoices Pharmacy

DATE: 7/26/13

JOHN E. SWALLOW
ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 30 July 13

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Allergychoices Inc., by:

Jeffrey Kessler, President
2800 National Dr., Ste 100
Onalaska, WI 54650
License no. 42-8984

12/10/12
Date

Kerry L. Moskol, Attorney for Respondent
Quarles & Brady LLP
33 East Main St., Ste 900
Madison, WI 53703

12/11/12
Date

Arthur Thexton, Compliance Attorney
Division of Legal Services and Compliance
P.O. Box 8935
Madison, WI 53708-8935

12/11/12
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	**FINAL DECISION AND ORDER**
ALLERGYCHOICES, INC., d/b/a ALLERGYCHOICES PHARMACY, RESPONDENT.	:	
	:	ORDER 0002288

Division of Legal Services and Compliance[1] Case No. 11 PHM 71

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Allergychoices, Inc.
2800 National Drive, Suite 100
Onalaska, WI 54650

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent Allergychoices, Inc., d/b/a Allergychoices Pharmacy, is licensed in the State of Wisconsin as a pharmacy, having license number 42-8984, first issued on December 14, 2009, and current through May 31, 2014. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 2800 National Drive, Suite 100, Onalaska, WI 54650. Respondent's pharmacy is engaged exclusively in the compounding of liquid sublingual immunotherapy (SLIT) preparations.

[1] The Division of Legal Services and Compliance was formerly known as the Division of Enforcement.

11. Presently, Respondent uses the following language in the successor to this particular piece of literature:

> Q: Can I mark up the cost of the prescription?
> A: No, Allergychoices is a retail pharmacy that prepares patient-named prescriptions, and like any other retail prescription, patient prescription charges must reflect actual retail pricing. Refer to your practice is standard pricing policy for any additional charges for staff time, office overhead and professional services that accompany, but are separate from, charges for prescriptions.

12. On rare occasion, a patient is thought to be intolerant to glycerin. On such occasions, Respondent's practice has been to compound the prescription using sterile water as a primary diluent, although some glycerin accompanies the active ingredient. Respondent does not have a protocol for assuring the safe delivery of such a prescription, nor is it given an appropriate expiration date (two weeks). Literature furnished by Respondent supporting glycerin as an effective preservative in lower concentrations did not, in fact, support Respondent's practice in all cases.

13. Respondent's labeling does not include the quantity or concentration of each active ingredient, in a manner which another health care practitioner could readily understand.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in Finding of Fact 3, Respondent violated Wis. Admin. Code § Phar 7.01(1)(e), in that a prescription may be delivered only to a patient's residence unless the Board has granted a variance permitting delivery elsewhere.

3. By the conduct described in Findings of Fact 4 and 7, Respondent violated Wis. Admin. Code § Phar 10.03(1), in that the pharmacy's financial arrangements and transactions were not always directly and exclusively between the patient and the pharmacy.

4. By the conduct described in Finding of Fact 9, Respondent violated Wis. Stat. §§ 450.10(1)(a)2. and 450.09(1)(a), in that every pharmacy shall be under the control of the managing pharmacist, and the managing pharmacist shall be responsible for the professional operations of the pharmacy.

5. By the conduct described in Finding of Fact 12, Respondent violated Wis. Admin. Code § Phar 10.03(2).

6. By the conduct described in Finding of Fact 13, Respondent violated Wis. Admin. Code § Phar 10.03(16).

7. As a result of the above violation, Allergychoices, Inc., is subject to discipline pursuant to Wis. Stat. § 450.10(1).

CERTIFICATE OF SERVICE

I hereby certify that on the 2 day of Aug., 2013, a true and correct copy of the foregoing STIPULATION AND ORDER was served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

ALLERGYCHOICES PHARMACY
2800 NATIONAL DR STE 100
ONALASKA WI 54650

Hand delivered copy to:

L. Mitchell Jones, Assistant Attorney General

Kim Lesh
Administrative Secretary
Division of Occupational
and Professional
Licensing

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
JOHN E. SWALLOW (U.S.B. 5802)
Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 146741
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSE OF **ALLERGYCHOICES PHARMACY** TO OPERATE AS A CLASS D OUT-OF-STATE PHARMACY IN THE STATE OF UTAH	)))))	STIPULATION AND ORDER CASE NO. DOPL 2013--

ALLERGYCHOICES PHARMACY ("Respondent") and the **DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Jeffrey Kessler is the President of Respondent pharmacy and is authorized to act as agent for and enter into binding agreements on behalf of Respondent.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby waives all administrative and judicial review as set forth in §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-46b-12 through R151-46b-15. Respondent and the Division hereby express their intent that that matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's licenses, to other persons and entities.

7. Respondent admits the following facts are true:

a. On or about March 3, 2011 Respondent was first licensed to operate as a Class B pharmacy and to dispense controlled substances within the State of Utah.

b. On or about December 10, 2012, Respondent voluntarily entered into a Stipulation, which is incorporated by reference into this Stipulation and Order and attached as Exhibit A, with the Wisconsin Pharmacy Examining Board ("Wisconsin Board"). The Wisconsin Board entered a Final Decision and Order in the matter, which is incorporated by reference into this Stipulation and Order and attached as Exhibit B.

c. The conduct described in subparagraph (b) above would constitute misconduct in the State of Utah.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(6) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

(a) Respondent shall pay a fine to the Division in the amount of $1,000.00 (one-thousand dollars), pursuant to Utah Code Ann. § 58-17b-504. One half of the fine, or $500.00 (five-hundred dollars) shall be stayed. If Respondent violates any term or condition of this Stipulation and Order, within two years of the effective date of this Stipulation and Order, the Division may take action to lift the stayed portion of the fine. Respondent shall pay the unstayed $500.00 portion of the fine within 90 days of the effective date of this Stipulation and Order.

(b) Respondent's licenses shall be publicly reprimanded for the conduct described in subparagraph 7(b) above.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order

and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent agrees that the time period for completion of that term or condition shall be set by the Board. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

BY: _____
RICHARD J. OBORN
Bureau Manager

DATE: 7/29/13

RESPONDENT

BY: _____
JEFFREY KESSLER
President
Allergychoices Pharmacy

DATE: 7/26/13

JOHN E. SWALLOW
ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 30 July 13

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

ALLERGYCHOICES PHARMACY
License Numbers: 53-01-009013
53-15-038857

File Number: 53-13-128100

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on October 18, 2013, charging Allergychoices Pharmacy, hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Pharmacy has admitted, by Stipulation submitted herewith, that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code; and

WHEREAS, the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-13-128100.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 02/12/14

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. The facts alleged in the Complaint dated October 18, 2013, are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order were as follows:

> In the written response to the Complaint, Respondent Pharmacy provided satisfactory evidence of compliance

with all terms of the Final Decision and Order issued by the Wisconsin Pharmacy Examining Board on February 13, 2013.

4. Dhafer Almaklani, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent and the Department expressly reserving the right to further proceedings should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 12-6-13

AGREED TO BY:

Michael B. Kachel, R.Ph.
Authorized Representative for
Allergychoices Pharmacy
Respondent Pharmacy

Dated: 12-2-13

This is the final page of a Consent Order and Stipulation in the matter of Allergychoices Pharmacy, File Number 53-13-128100, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included.

CBS

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

ALLERGYCHOICES PHARMACY
License Number: 53-01-009013

File Number: 53-13-128100

ADMINISTRATIVE COMPLAINT

NOW COMES the Michigan Department of Licensing and Regulatory Affairs, hereafter Complainant, by Carole H. Engle, Director, Bureau of Health Care Services, and files this Complaint against Allergychoices Pharmacy, hereafter Respondent Pharmacy, alleging upon information and belief as follows:

1. The Michigan Board of Pharmacy, hereafter Board, is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 16226 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline Respondents for violations of the Public Health Code.

2. Respondent Pharmacy is currently licensed to practice as a pharmacy in the state of Michigan, has a current controlled substance license, and has an address of record with Complainant of Onalaska, Wisconsin.

3. On February 13, 2013, the Wisconsin Pharmacy Examining Board issued a Final Decision and Order whereby Respondent Pharmacy was, in part, reprimanded, and ordered to forfeit $1,000.00 and pay $3,500.00 in costs. The disciplinary action was based on Respondent Pharmacy's mailing and billing practices. A copy of the Final Decision and Order, marked Exhibit A, is attached and incorporated.

COUNT I

The foregoing action in the state of Wisconsin, as set forth in paragraph 3, constitutes a final adverse administrative action by a licensure, registration, disciplinary, or certification board involving the holder of, or an applicant for, a license or registration regulated by another state or a territory of the United States, in violation of section 16221(b)(x) of the Public Health Code, supra.

WHEREFORE, Complainant requests that the within Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

RESPONDENT PHARMACY IS HEREBY NOTIFIED that, pursuant to section 16231(7) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Carole H. Engle, Director,

Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

RESPONDENT PHARMACY IS FURTHER NOTIFIED that, pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

Carole H. Engle, Director
Bureau of Health Care Services

DATED: 10-18-13

Attachment

This is the final page of an Administrative Complaint in the matter of Allergychoices, File Number 53-13-128100, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

CBS

PDH

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY OF SOUTH CAROLINA

In the Matter of: **ALLERGY CHOICES PHARMACY** Permit No. PY.10933 OIE # 2013-53 Respondent.	**CONSENT AGREEMENT**

By agreement of the Board of Pharmacy ("the Board") and the above-named Respondent, the following disposition of this matter is entered pursuant to the provisions of S.C. Code Ann. § 1-23-320(f) (1976, as amended), in lieu of, inter alia, a hearing before the Board, a hearing officer or panel appointed by the Board/Commission.

FINDINGS OF FACT

1. Respondent was permitted as a Non Resident Pharmacy in the State of South Carolina at all times relevant to the matters asserted in this case. The Board has jurisdiction over this matter.

2. Respondent admits the following:

    a. Respondent was sanctioned by the Wisconsin Board of Pharmacy for delivering prescriptions to physicians and accepting payment from the physicians. Wisconsin law prohibits a pharmacy from using a physician as an agent. Respondent was reprimanded, fined $1,000, and required to label all compounded prescriptions in compliance with USP 795.

3. Respondent further admits that as a result of the previous admissions herein, Respondent has violated S.C. Code Ann. § 40-1-110(1)(b) (1976, as amended).

4. Respondent waives any further findings of fact with respect to this matter.

CONCLUSIONS OF LAW

1. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary or corrective action under South Carolina Code Ann. §§ 40-43-140 and 40-1-120 (Supp. 2013). Respondent hereby waives any further conclusions of law with respect to this matter.

2. Respondent has full knowledge that Respondent has the right to a hearing and to be represented by counsel in this matter, and freely, knowingly, and voluntarily waives such rights by entering into this Consent Agreement. Respondent understands and

5-20-14

3650

agrees that by entering into this Consent Agreement, Respondent voluntarily relinquishes any right to judicial review of Board action(s), which may be taken concerning any related matters. Respondent understands and agrees that this Consent Agreement will not become effective unless and until approved by the Board. Respondent understands and agrees that a representative of the General Counsel's Office and Respondent may be present during presentation of this Consent Agreement to the Board. Respondent understands and agrees that if this Consent Agreement is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the right of the Board to adjudicate this matter.

THEREFORE, IT IS AGREED WITH RESPONDENT'S CONSENT THAT:

1. Respondent shall be **publicly reprimanded.**

2. Respondent agrees to comply with all state and federal statutes and regulations governing the practice of pharmacy.

3. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives in the investigation of Respondent's practice and compliance with the provisions of this Consent Agreement. Respondent may be required to furnish the Board with additional information as may be deemed necessary by the Board or its representatives. In addition to such requests, the Board in its discretion may require Respondent to submit further documentation regarding Respondent's practice, and it is Respondent's responsibility to comply with all reasonable requests in a timely fashion. Failure to comply with such requests is a violation of this Consent Agreement, and may result in the immediate temporary suspension of Respondent's Non Resident Permit, pending a hearing and until further Order of the Board.

4. Pursuant to the South Carolina Freedom of Information Act, this Consent Agreement, with attachments, is a public document, and this action will be reported to the National Practitioner Data Bank in accordance with P.L. 99-660.

5. This Consent Agreement shall take effect upon service of an executed copy on the Respondent or counsel.

AND IT IS SO AGREED.

STATE BOARD OF PHARMACY

6-19-2014
Date

[redacted]
Chairman of the Board

[redacted]
MICHAEL B. KACHEL
Respondent

1-14-14
DATE

[redacted]
WITNESS OR ATTORNEY

1.14.14
DATE

[redacted]
PATRICK D. HANKS
Assistant General Counsel
South Carolina Department of Labor,
Licensing & Regulation

6/20/14
DATE

05-20-14
3652 [redacted]

3-6-15

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ALLERGY CHOICES PHARMACY	)	
	)	
Non-Resident Pharmacy Permit Numbers: 112827/201471	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Allergy Choices Pharmacy which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Allergy Choices Pharmacy through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Allergy Choices Pharmacy violated the provisions of law based upon the conduct set out in Counts Two and Three of the Statement. Counts One and Four are dismissed with prejudice.

2. Allergy Choices Pharmacy shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Allergy Choices Pharmacy expressly waive its rights pursuant to the

Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Allergy Choices Pharmacy further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Allergy Choices Pharmacy hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Allergy Choices Pharmacy acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Allergy Choices Pharmacy's permit, including, but not limited to revocation.

6. Allergy Choices Pharmacy acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Allergy Choices Pharmacy acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 20th of March, 2015.

ALLERGY CHOICES PHARMACY

BY: _____

ITS: President

_____

Randall R. Fearnow, attorney for Allergy Choices Pharmacy

ALABAMA STATE BOARD OF PHARMACY

By: _____
Dan McConaghy, President

By: _____
James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
ALLERGY CHOICES PHARMACY	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy	)	
Permit Numbers: 112827/201471	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Allergy Choices Pharmacy
c/o Mark A. Allen
2800 National Drive, Suite 100
Onalaska, WI 54654

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on March 24, 2015 at 1:00 p.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Allergy Choices Pharmacy should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Allergy Choices Pharmacy has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(6) based upon any or all of the following:

(a) Sanction by the Wisconsin Board of Pharmacy for delivering prescriptions to physicians and accepting payment from physicians as set out in the

Consent Agreement entered by the South Carolina Board of Pharmacy on June 20, 2014, a copy of the same being attached hereto as Exhibit "A".

(b) The Consent Order entered by the South Carolina Board of Pharmacy referenced above.

(c) The Consent Order entered by the Michigan Board of Pharmacy on February 12, 2014, a copy of the same being attached hereto as Exhibit "B".

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(f) based upon any or all of the allegations of the preceding Counts.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16th day of January, 2015.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT A

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY OF SOUTH CAROLINA

In the Matter of: **ALLERGY CHOICES PHARMACY** Permit No. PY.10933 OIE # 2013-53 Respondent.	**CONSENT AGREEMENT**

By agreement of the Board of Pharmacy ("the Board") and the above-named Respondent, the following disposition of this matter is entered pursuant to the provisions of S.C. Code Ann. § 1-23-320(f) (1976, as amended), in lieu of, inter alia, a hearing before the Board, a hearing officer or panel appointed by the Board/Commission.

FINDINGS OF FACT

1. Respondent was permitted as a Non Resident Pharmacy in the State of South Carolina at all times relevant to the matters asserted in this case. The Board has jurisdiction over this matter.

2. Respondent admits the following:

   a. Respondent was sanctioned by the Wisconsin Board of Pharmacy for delivering prescriptions to physicians and accepting payment from the physicians. Wisconsin law prohibits a pharmacy from using a physician as an agent. Respondent was reprimanded, fined $1,000, and required to label all compounded prescriptions in compliance with USP 795.

3. Respondent further admits that as a result of the previous admissions herein, Respondent has violated S.C. Code Ann. § 40-1-110(1)(b) (1976, as amended).

4. Respondent waives any further findings of fact with respect to this matter.

CONCLUSIONS OF LAW

1. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary or corrective action under South Carolina Code Ann. §§ 40-43-140 and 40-1-120 (Supp. 2013). Respondent hereby waives any further conclusions of law with respect to this matter.

2. Respondent has full knowledge that Respondent has the right to a hearing and to be represented by counsel in this matter, and freely, knowingly, and voluntarily waives such rights by entering into this Consent Agreement. Respondent understands and

DEC 04 2014

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agrees that by entering into this Consent Agreement, Respondent voluntarily relinquishes any right to judicial review of Board action(s), which may be taken concerning any related matters. Respondent understands and agrees that this Consent Agreement will not become effective unless and until approved by the Board. Respondent understands and agrees that a representative of the General Counsel's Office and Respondent may be present during presentation of this Consent Agreement to the Board. Respondent understands and agrees that if this Consent Agreement is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the right of the Board to adjudicate this matter.

THEREFORE, IT IS AGREED WITH RESPONDENT'S CONSENT THAT:

1. Respondent shall be **publicly reprimanded.**

2. Respondent agrees to comply with all state and federal statutes and regulations governing the practice of pharmacy.

3. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives in the investigation of Respondent's practice and compliance with the provisions of this Consent Agreement. Respondent may be required to furnish the Board with additional information as may be deemed necessary by the Board or its representatives. In addition to such requests, the Board in its discretion may require Respondent to submit further documentation regarding Respondent's practice, and it is Respondent's responsibility to comply with all reasonable requests in a timely fashion. Failure to comply with such requests is a violation of this Consent Agreement, and may result in the immediate temporary suspension of Respondent's Non Resident Permit, pending a hearing and until further Order of the Board.

4. Pursuant to the South Carolina Freedom of Information Act, this Consent Agreement, with attachments, is a public document, and this action will be reported to the National Practitioner Data Bank in accordance with P.L. 99-660.

5. This Consent Agreement shall take effect upon service of an executed copy on the Respondent or counsel.

AND IT IS SO AGREED.

05-20-14

STATE BOARD OF PHARMACY

6-19-2014
Date

Chairman of the Board

MICHAEL B. KACHEL
Respondent

1-14-14
DATE

WITNESS OR ATTORNEY

1.14.14
DATE

PATRICK D. HANKS
Assistant General Counsel
South Carolina Department of Labor,
Licensing & Regulation

6/20/14
DATE

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EXHIBIT B

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

RECEIVED
DEC 05 2013
DEPARTMENT OF LICENSING & REGULATORY AFFAIRS
BUREAU OF HEALTHCARE SERVICES
HEALTH PROFESSIONS DIVISION
ENFORCEMENT SECTION - ENFORCEMENT UNIT

In the Matter of

ALLERGYCHOICES PHARMACY
License Numbers: 53-01-008013
53-15-038857

File Number: 53-13-128100

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on October 18, 2013, charging Allergychoices Pharmacy, hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Pharmacy has admitted, by Stipulation submitted herewith, that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code; and

WHEREAS, the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

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Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-13-128100.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 02/12/14

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. The facts alleged in the Complaint dated October 18, 2013, are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order were as follows:

> In the written response to the Complaint, Respondent Pharmacy provided satisfactory evidence of compliance

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with all terms of the Final Decision and Order issued by the Wisconsin Pharmacy Examining Board on February 13, 2013.

4. Dhafer Almaklani, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent and the Department expressly reserving the right to further proceedings should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 12-6-13

AGREED TO BY:

Michael B. Kachel, R.Ph.
Authorized Representative for
Allergychoices Pharmacy
Respondent Pharmacy

Dated: 12-2-13

This is the final page of a Consent Order and Stipulation in the matter of Allergychoices Pharmacy, File Number 53-13-128100, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included.

CBS

LOUISIANA BOARD OF PHARMACY
BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

ALLERGY CHOICES, INC. D/B/A ALLERGYCHOICES PHARMACY

PHARMACY PERMIT NO. 5859 **CASE NO. 15-0385**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy on March 9, 2016 at the Louisiana Board of Pharmacy (hereinafter "Board") office, 3388 Brentwood Drive, Baton Rouge, Louisiana, in the matter of **ALLERGY CHOICES, INC. D/B/A ALLERGY CHOICES, INC. D/B/A ALLERGYCHOICES PHARMACY** (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 5859, 2731 National Dr., Onalaska, WI 54650-8784, with Michael B. Kachel present.

WHEREAS, Respondent was disciplined by Board Order issued by the Alabama Board of Pharmacy on or about March 20, 2015. Respondent failed to report this disciplinary action on its Renewal Application for its Louisiana permit for Year 2016.

WHEREAS, information received and/or gathered by the Board produced evidence indicating that Respondent violated the following laws and regulations:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(6): Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(2): Attempted to or obtained a license, registration, certificate, permit or any other designation deemed necessary to engage in the practice of pharmacy by fraud or misrepresentation.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

PHARMACY PERMIT NO. 5859 belonging to ALLERGY CHOICES, INC. D/B/A ALLERGYCHOICES PHARMACY is assessed a fine of $5,000.00 and ordered to reimburse the Board $250.00 in administrative hearing costs, with total payment due the Board of $5,250.00, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter; and Respondent waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting.

However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon Respondent signing the Consent Agreement.

Respondent agrees to provide and does provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: 1700025707

Medicare Provider Number (if in the possession of one): _____

I, MICHAEL B KACHEL, authorized representative on behalf of ALLERGY CHOICES, INC. D/B/A ALLERGYCHOICES PHARMACY, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

SIGNED, AGREED TO AND ENTERED ON THIS 15 DAY OF MARCH, 2016.

ALLERGY CHOICES, INC. D/B/A ALLERGYCHOICES PHARMACY
PHARMACY PERMIT NO. 5859

BY:
Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
3388 Brentwood Drive
Baton Rouge, LA 70808
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 4, 2016, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron
President and Hearing Officer for the Board

AGREED BOARD ORDER #L-16-037

RE: IN THE MATTER OF ALLERGYCHOICES PHARMACY (PHARMACY LICENSE #25064)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 25064 issued to Allergychoices Pharmacy (Respondent), 2731 National Drive, Onalaska, Wisconsin 54650.

By letter dated August 10, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(3) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015), as alleged in the Count below.

The conduct described in the Consent Order of the Louisiana Board of Pharmacy is substantially similar to conduct described in:

> Section 565.002(a)(3) and (10) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and
>
> Section 281.8(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016).

COUNT

On or about May 4, 2016, the Louisiana Board of Pharmacy entered a Consent Order against the pharmacy permit number 5859 held by Allergychoices Pharmacy. The Order was based on allegations that Allergychoices Pharmacy failed to report on its 2016 renewal application that on or about March 20, 2015, the Alabama Board of Pharmacy entered a Consent Order against its Alabama non-resident pharmacy permit. The Consent Order imposed a $5,000 fine.

By letter dated August 10, 2016, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Jeffery Kessler, Corporate President, Allgerychoices, Inc., on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and

waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of November, 2016.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Jeffery Kessler, Corporate President, Allergychoices, Inc.
For and on behalf of Allergychoices Pharmacy

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

IN THE MATTER OF	*	**BEFORE THE**
ALLERGYCHOICES, INC.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHARMACY**
Permit No. P04854	*	**Case No. PI-14-063/14-563**

* * * * * * * * * * * * * *

PRE-CHARGE CONSENT ORDER

Background

On February 13, 2013, Allergychoices, Inc. (the "Respondent"), Permit No. P04854, entered into a stipulation with the Wisconsin Pharmacy Examining Board concerning the Respondent's practice of sending patient-specific compounded prescriptions to a physician's office for resale to the patient. The Wisconsin Pharmacy Examining Board reprimanded the Respondent's permit and imposed a $1,000 fine and $3,500 in costs. The Respondent informed the Maryland Board of Pharmacy (the "Board") of the action taken by the Wisconsin Board and subsequently informed the Board of further reciprocal actions taken by the Boards of Pharmacy in Utah, Michigan, South Carolina, and Alabama based on the conduct at issue in the Wisconsin stipulation. On May 16, 2016, the Respondent notified the Board that the Louisiana Board of Pharmacy imposed a fine on the Respondent based on the Respondent's failure to disclose the Alabama action on a renewal application.

In lieu of instituting formal proceedings against the Respondent, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board proposed, and the Respondent agreed, to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent possessed a Maryland non-resident pharmacy permit, Permit No. P04854, and operated as a non-resident pharmacy in Onalaska, Wisconsin. The Respondent's permit was initially issued on November 26, 2008. The Respondent's permit is active and is set to expire on May 31, 2018.
2. On February 13, 2013, the Respondent entered into a stipulation with the Wisconsin Pharmacy Examining Board related to its compounding and dispensing of liquid sublingual immunotherapy ("SLIT") preparations. Specifically, the Wisconsin Pharmacy Examining Board found the following facts:
    a. The Respondent compounded patient-specific prescriptions which it then, in over 80% of cases, shipped directly to the prescriber's office to allow the prescriber to observe the initial administration to the patient;
    b. In the majority of cases, the Respondent billed the physician for the medication, and the physician sought reimbursement from the patient;
    c. In April 2007, the Respondent prepared a document titled "Answers to Common Questions about SLIT for Medical Staff" in which it stated it was "not aware of specific statutes that prohibit physicians from marking up a compounded prescription";[1]
    d. In rare cases, with a patient thought to be intolerant to glycerin, the Respondent compounded its prescriptions using sterile water as a primary diluent, but it did not have protocols for assuring the safe delivery of such

[1] The Respondent later updated the document to state that its products could not be marked up for resale by a third-party physician.

prescriptions and it did not give them appropriate two-week expirations dates; and

e. The Respondent's labeling did not include the quantity or concentration of the active ingredients in a manner easily understandable by other health care practitioners.

3. The Wisconsin Board based its action against the Respondent on a finding that the practice of compounding drugs for resale constituted manufacturing, which the Respondent was neither licensed to do in Wisconsin nor registered to do with the FDA. The Respondent argued that it was simply dispensing the drugs to the patients through the physicians who were acting as agents for the patients, which the Wisconsin Board found to be improper in and of itself.

4. The Wisconsin Board reprimanded the Respondent's license, fined the Respondent $1,000, and imposed costs of $3,500. The Respondent also agreed to label all compounded prescriptions in accordance with USP 795.

5. On September 4, 2013, the Board received notification from the Respondent that the Utah Board of Pharmacy had taken reciprocal action against the Respondent based on the Respondent's stipulation with the Wisconsin Board. The Utah Board reprimanded the Respondent's license and fined the Respondent $1,000, half ($500) of which was stayed.

6. On or about October 21, 2015, the Respondent applied to the Board for relocation. On its application, the Respondent disclosed that the Boards of Pharmacy in Michigan, South Carolina, and Alabama also took the following reciprocal actions against the Respondent based on the Respondent's stipulation with the Wisconsin Board:

a. On or about February 12, 2014, the Michigan Board of Pharmacy issued a reprimand against the Respondent and imposed a $500 fine;

b. On or about June 19, 2014, the State Board of Pharmacy of South Carolina issued a reprimand against the Respondent; and

c. On or about March 20, 2015, the Alabama State Board of Pharmacy imposed a $1,000 fine against the Respondent.

7. Finally, on May 16, 2016, the Respondent informed the Board that on March 15, 2016, the Louisiana Board of Pharmacy imposed a $5,000 fine and $250 in costs against the Respondent for the Respondent's failure to report the disciplinary action in Alabama on its Louisiana renewal application.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§ 12-409(b), 12-403(c)(9), (g), and 12-313(b)(24), (25), and COMAR 10.34.19.

ORDER

Based on the agreement of the parties and an affirmative vote of a majority of the Board, it is this 5th day of August, 2016, hereby:

ORDERED that within 30 days of the effective date of this Consent Order, the Respondent shall pay a fine in the amount of $1,000, payable to the Maryland Board of Pharmacy; and be it further,

ORDERED that the Respondent shall practice in Maryland at all times in accordance with the Maryland Pharmacy Act; and be it further,

ORDERED that failure to comply with the terms and conditions of this Consent Order, including failure to pay the required fine, constitutes a violation of this Consent Order, and the Board, in its discretion, after notice and an opportunity for a hearing before the Board, may impose any appropriate sanction under the Maryland Pharmacy act; and be it further

ORDERED that the Respondent shall bear all expenses associated with this order; and be it further

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to Md. Code Ann., General Provisions § 4-333(b)(6).

8/5/16
Date

Mitra Gavgani, President
Maryland Board of Pharmacy

CONSENT

1. By signing this Consent, the Respondent, Allergychoices, Inc., submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Respondent the right to a full evidentiary hearing. The Respondent consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Respondent would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf, and to all other substantive and procedural protections provided by law.
2. By signing this Consent, the Respondent waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Respondent acknowledges that this is a formal order of the Board and as such is a public document.
4. The Respondent acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. The Respondent signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Respondent fully understands the language, meaning, and effect of this Consent Order.

ALLERGYCHOICES, INC.
Permit No. P04854

8-2-16
Date

Michael B. Kachel, RPh
Director of Pharmacy
Allergychoices, Inc.

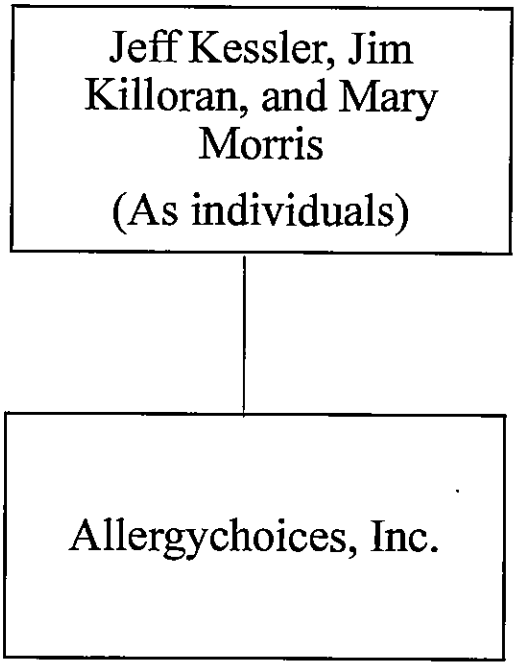
STATE OF Wisconsin
COUNTY/CITY OF LaCrosse :

I hereby certify that on this 2nd day of August, 2016, before me, a Notary Public of the State of Wisconsin and County/city aforesaid, personally appeared Michael B. Kachel, on behalf of ALLERGYCHOICES, INC., and made an oath in due form that the foregoing Consent was his voluntary act and deed.

Misty Lins
Notary Public
My commission expires: 02/21/20

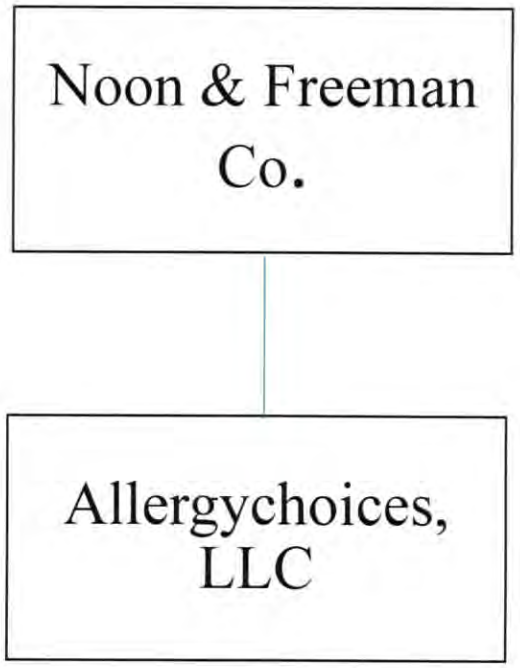
Allergychoices, Inc.

Pre-Organizational Chart



Allergychoices, LLC

Post-Organizational Chart



Allergychoices, LLC

Officer and Ownership Information

Name	Title
Eugene Kakaulin	Chief Executive Officer

The pharmacy is wholly owned by:
Allergychoices, LLC
2731 National Drive
Onalska, WI 54650
FEIN: 39-2012025

Allergychoices, LLC is wholly owned by:
Noon & Freeman Co.
777 Brickell Ave 500-95053
Miami, FL 33131
FEIN: 99-0776680

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Business e-Profile ID:	621474		**Inspection Information**
Legal Business Name:	Allergychoices Inc.	**Conference Call Date:**	N/A
Doing Business As (DBA):	Allergychoices Pharmacy	**Start Time: 24-hour format (13:00)**	N/A
Address:	2731 National Dr	**End Time: 24-hour format (13:00)**	N/A
City:	Onalaska	**Onsite Inspection Date(s):**	12/20/2023
State:	Wisconsin	**Start Time(s): 24-hour format (13:00)**	14:15
Zip Code:	54650	**End Time(s): 24-hour format (13:00)**	17:30
Telephone number:	608-793-1580	**Inspector Name:**	Katie Busroe, RPh, BCSCP
Toll free number:	866-793-1680	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	608-793-1571	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.allergychoices.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The facility is encouraged to read the inspection report in its entirety and carefully.
Specific Module(s) and/or Question(s) to which the facility may want to consider further response are:
General Pharmacy - 67.01
Nonsterile -1.0, 1.5, 3.0. 3.2, 3.3, 4.0, 6.0, 6.3, 15.0, 15.2, 26.1, 26.2, 26.3, 31.0, 31.4, 58.0, and 58.8

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:00	17:00	
Tuesday	8:00	17:00	
Wednesday	8:00	17:00	
Thursday	8:00	17:00	
Friday	8:00	17:00	
Saturday	8:00	12:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Michael Kachel	mkachel@allergychoices.com	273901
Nonsterile Compounding Supervisor	Michael Kachel	mkachel@allergychoices.com	273901
Sterile Compounding Supervisor	N/A	N/A	N/A
Hazardous Compounding Supervisor	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Michael Kachel	PIC	Y
2	Maci Sprosty	RPh	Y
3	Justin O'Driscoll	RPh	Y
4	Sharon McKinney	Tech	Y
5	Kristine West	Tech	Y
6	Sara Schermerhorn	Tech	Y
7	Chris Staab	Tech	Y
8	Brooklyn Block	Tech	Y
9	Ann Staab	VP of Operations	N/A
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Wisconsin Pharmacy Examining Board	Allergychoices Pharmacy	Pharmacy	9342-42 Exp: 5/31/2024

Inspector Notes: List states in which Non-Resident licenses are held: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
Pharmacy does not stock or dispense insulin including ReliOn insulin. Pharmacy does not stock or compound with semaglutide. Pharmacy does not use any platforms that are a marketplace for pharmacies to buy, sell, and bid on overstock and short dated drugs.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_Gen67.01_AllergychoicesPharmacy_Onalaska_WI	Document mailed to the patients for them to complete regarding their medical history.
Doc02_NS23.1_AllergychoicesPharmacy_Onalaska_WI	Letco certificate of analysis for glycerin USP
Doc03_NS23.1_AllergychoicesPharmacy_Onalaska_WI	pharma nobis certificate of analysis for glycerin USP

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements	
CNSPs for INDs		CSPs for INDs	
CNSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list		CSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list	
CNSPs sold OTC		CSPs sold OTC	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific:		Patient specific:	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (eg non patient-specific):		Distributed (eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Creams		Injections including infusions	
Gels		Irrigations for internal body cavities (eg bladder or peritoneal cavity)	
Ointments		Ophthalmic dosage forms	
Lotions		Aqueous preparations for pulmonary inhalation	
Nasal and sinus preparations:		Baths and soaks for live organs and tissues	
Nasal sprays		Implants/ Pellets	
Nasal irrigations		Other (please list):	
Other (please list):	Sublingual immunotherapy (allergy drops)		

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	1,200	Total Pharmacists:	3
Nonsterile Compounding Room size:	800	Number of Compounding Pharmacists	3
Nonsterile Compounding powder hoods number:	0	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Student Interns:	0
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	N/A	Total Technicians:	6
Sterile Compounding Ante Room size:	N/A	Number of Compounding Technicians	6
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are certified?	6
Sterile Compounding Number LAFW hoods/areas:	N/A	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	N/A	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	N/A	Total Other Unlicensed Personnel:	1 (VP of Operations, not in the licensed pharmacy)
Negative Pressure Sterile HD Room size:	N/A	Ratio #Tech:#RPh present at time of inspection:	5:3
Sterile HD Compounding Number of BSC hoods:	N/A	Total Pharmacist Hours Per Week:	~120 plus
Sterile HD Compounding Number of CACI hoods:	N/A	Total Technician Hours Per Week:	240

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	200	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	100%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	35	0	November 2023
Alaska (AK)	16	0	November 2023
Arizona (AZ)	149	0	November 2023
Arkansas (AR)	32	0	November 2023
California (CA)	588	0	November 2023
Colorado (CO)	123	0	November 2023
Connecticut (CT)	60	0	November 2023
Delaware (DE)	26	0	November 2023
District of Columbia (DC)	34	0	November 2023
Florida (FL)	294	0	November 2023
Georgia (GA)	139	0	November 2023
Hawaii (HI)	5	0	November 2023
Idaho (ID)	30	0	November 2023
Illinois (IL)	197	0	November 2023
Indiana (IN)	110	0	November 2023
Iowa (IA)	15	0	November 2023
Kansas (KS)	30	0	November 2023
Kentucky (KY)	44	0	November 2023
Louisiana (LA)	46	0	November 2023
Maine (ME)	12	0	November 2023
Maryland (MD)	88	0	November 2023
Massachusetts (MA)	157	0	November 2023
Michigan (MI)	75	0	November 2023
Minnesota (MN)	242	0	November 2023
Mississippi (MS)	10	0	November 2023
Missouri (MO)	131	0	November 2023
Montana (MT)	53	0	November 2023

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	29	0	November 2023
Nevada (NV)	48	0	November 2023
New Hampshire (NH)	19	0	November 2023
New Jersey (NJ)	128	0	November 2023
New Mexico (NM)	28	0	November 2023
New York (NY)	385	0	November 2023
North Carolina (NC)	142	0	November 2023
North Dakota (ND)	16	0	November 2023
Ohio (OH)	113	0	November 2023
Oklahoma (OK)	38	0	November 2023
Oregon (OR)	61	0	November 2023
Pennsylvania (PA)	178	0	November 2023
Rhode Island (RI)	15	0	November 2023
South Carolina (SC)	62	0	November 2023
South Dakota (SD)	11	0	November 2023
Tennessee (TN)	66	0	November 2023
Texas (TX)	387	0	November 2023
Utah (UT)	61	0	November 2023
Vermont (VT)	14	0	November 2023
Virginia (VA)	134	0	November 2023
Washington (WA)	162	0	November 2023
West Virginia (WV)	8	0	November 2023
Wisconsin (WI)	124	0	November 2023
Wyoming (WY)	7	0	November 2023
Other:			

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General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	At least 40 hours/week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	The parent company, Allergy Choices, Inc., is at this address but does not have access to the pharmacy. The pharmacy has its own alarm system in addition to the building alarm system.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	Patients can request refills via text messages and can order a refill through the website patient portal using a prescription number, date of birth, name. The request goes directly into the computer system, LifeFile.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	Not needed.
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Maci Sprosty, RPh; Justin O'Driscoll, RPh; Sharon McKinney, tech; Sara Schermerhorn, tech.

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National Association of Boards of Pharmacy®
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Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Finding	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Less than 1% are mailed to the provider/facility for administration in WI and less than 1% to other states. If the state law allows, the pharmacy documents the patient's permission to mail the prescription to the provider for the initial dose.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Inspection Date: 12/20/2023

		Finding	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	WI inspected 8/15/2016 for a change of location. WI does not inspect on a regular basis.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	Ten to twelve years ago the pharmacy was inspected by NABP on behalf of IA.
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	Pharmacy has a waiver from almost every state to not report zero for controlled substances. Pharmacy reports to NE for all prescriptions dispensed to NE patients.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	

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		Finding	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Keep records seven years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	There are very few e-prescriptions, which are printed and electronic.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Computer system, LifeFile, tracks every key stroke and does not allow a prescription to be deleted.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	There is a statement in the P&P to follow the most stringent law. The three pharmacists work together to know which laws are most stringent and if needed, have reminders posted in the pharmacy.

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		Finding	Notes
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Employee provides a copy of the license and the PIC verifies on the BOP website with each renewal, every 2 years.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	PIC verifies on the BOP website with each renewal, every 2 years.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	WI is 4:1, pharmacy is usually 2:1.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The building is alarmed and the pharmacy has a separate alarm with only pharmacist having the key fob and key. There is a camera in the area prior to the pharmacy door and motion sensors. The alarm system is centrally monitored by WH International.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	PIC would stay until pharmacy is secured.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	

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		Finding	Notes
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	Yes	Pharmacy destroys returned prescriptions. Reviewed the destruction logs.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Stericycle.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Stericycle for Sharps containers. Frequency is as needed.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	One patient picked up a prescription in 2020 and one patient picked up a prescription on two different days in 2023. There is a private area where the patient is counseled partitioned off from the walk-in lobby.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	Controlled room temperature is monitored by La Crosse Alerts electronically and continuously. 72.6°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process.*	Yes	Pharmacy uses La Crosse Alerts temperature and humidity monitoring that electronically monitors and records the temperature and humidity every 15 minutes. Excursions are texted and emailed to the PIC.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	There is a separate refrigerator/freezer for food.

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		Finding	Notes
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Pharmacy uses ExcursionTrack by LABRepCo which records a max and min with a range of 2°C to 8°C and is accessible for 5 years. An audible and visual alarm notifies of an excursion.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	4.53°C.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen prescription drugs stocked or dispensed.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Pharmacy has a contract with a company to provide a generator.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Pharmacy would contact the building owners who have a contract with the local HVAC company.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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		Finding	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe*	Yes	Pharmacy only orders allergenic extracts from the manufacturers. Glycerin, an OTC used as a vehicle, is obtained from Letco/Fagron.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	ALK-Abello, Greer, and Jubilant.
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	No	Glycerin, an OTC used as a vehicle, is obtained from Letco/Fagron.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	N/A	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	N/A	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process*	Yes	Verified on state BOP websites.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	N/A	All prescription drugs are obtained directly from the manufacturers.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	All products are visually inspected upon arrival. If anything is unusual the manufacturer is contacted.

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		Finding	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	Direct purchase statement is on the invoice from the manufacturers.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	

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		Finding	Notes
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Pharmacy utilizes a computerized perpetual inventory.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Have not had this situation, but would report to local law enforcement and WI BOP.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Pharmacy checks quarterly and the allergenic extracts must have at least a 9 month expiration date. There is no OTC section.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	

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		Finding	Notes
60.02	How often is active-stock examined for drugs past the expiration date?		Quarterly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	Pharmacy only dispensed non-sterile compounds which are compounded patient specific pursuant to a prescription and mailed the same day as compounded.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Technicians or pharmacists enter profile data and update with each interaction with the patient.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	No veterinary prescriptions.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process*	Yes	Have not had this situation, but would contact the prescriber and local law enforcement.

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Inspection Date: 12/20/2023

		Finding	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Pharmacy is familiar with prescribers and creates an allergenic extracts list customized to each practice or prescriber.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both*	Yes	Non-controlled substances only. Rarely used, 99% of prescriptions are faxed.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	Pharmacy does not have a DEA registration and does not stock or dispense controlled substances.
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Pharmacist checks the patient information that is entered by a technician. Pharmacist enters the prescription data. The compounding technician reviews the prescription data and a second pharmacist performs the final check of the prescription data after the compounding. Barcode scanning is utilized.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	This pharmacy only dispenses non-sterile compounded sublingual allergy drops compounded from allergenic extracts. The DUR is manual and is done by the pharmacist at the time of prescription data entry, checking for glycerin allergy or sensitivity and if the patient is utilizing the allergy drops appropriately.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR*	No	Pharmacy attempts to obtain all other drugs and disease states for the patients but is not always successful. This pharmacy only dispenses compounded sublingual allergy drops compounded from allergenic extracts using glycerin as a vehicle. The pharmacist does manually check for a glycerin allergy or sensitivity and if the patient is utilizing the allergy drops appropriately. See Doc01_Gen67.01_AllergychoicesPharmacy_Onalaska_WI.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Some prescribers supply the pharmacist with the blood work/labs of the patient's allergies.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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		Finding	Notes
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Pharmacy has exemptions from reporting to almost all PMPs because the pharmacy does not dispense controlled substances. The exception is NE which requires all dispensed prescriptions to be reported.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	N/A	Pharmacy does not dispense controlled substances.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Pharmacist documents DUR in the notes in the patient profile.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	No	Performed manually by the pharmacist.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	No veterinary prescriptions.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Pharmacist performs the final check prior to dispensing using barcode scanning technology.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Per PIC, labels are per state and federal law.

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		Finding	Notes
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	LifeFile.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Place in a locked shred bin for Confidential Records, Inc to shred.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Finding	Notes
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	There was one patient pick up in 2020 and one person picked up a prescription on two different dates in 2023.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for <u>delivered</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	Pharmacy does not deliver prescriptions.

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		Finding	Notes
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Pharmacy provides printed information, a toll-free number, and pharmacist attempts to telephone the patient.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	Pharmacy only dispenses compounded sublingual allergy drops.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	Pharmacy only dispenses compounded sublingual allergy drops.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn)*	N/A	Pharmacy only dispenses compounded sublingual allergy drops.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Documented on paper for pick-ups or in the patient profile on computer for mailed prescriptions.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation)*	Yes	The phone is forwarded after hours, routing calls to the PIC's work cell.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list*	N/A	

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		Finding	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	PIC.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Both.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Hard copy.

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		Finding	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*	Yes	PIC with each event of a medication error reaching the patient and internal errors are quarterly.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	No formulary.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quarterly.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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		Finding	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Have not had this situation but would if warranted.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	Have not had this situation but would if warranted.
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	No DME equipment or devices.
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Annually.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)			
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, go to compliance statements.***	No		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	6.2, 11

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		Observation	Inspector Notes	USP Reference(s)
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***	No	There is no P&P addressing temperature monitoring.	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***	N/A	Pharmacy does not compound with API or any component that could generate airborne chemical particles. All non-sterile compounding is done using manufactured allergenic extracts in a 50% glycerin/50% distilled water vehicle.	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	7.1, 11

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		Observation	Inspector Notes	USP Reference(s)
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	11, 13.1

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		Observation	Inspector Notes	USP Reference(s)
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspecto r should answer statement as N/A.***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***	Yes	This is in the P&P but does not have a number. Revised November 2023. Reviewed during inspection.	12.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes	Pharmacy has named all 3 pharmacists as designated persons.	1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4

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		Observation	Inspector Notes	USP Reference(s)
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No	Reviewed training for all three pharmacists and six technicians.	2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	No		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	No		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3

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		Observation	Inspector Notes	USP Reference(s)
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes	Only garb is disposable gloves.	3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	No	Only components are manufactured allergenic extracts and glycerin 50%/distilled water 50% as the vehicle. Pharmacy did not have any SDS.	3.3

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		Observation	Inspector Notes	USP Reference(s)
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	N/A	No additional garb is needed. Compounders wear gloves. The compounding process is to draw up manufactured allergenic extract(s) with a syringe(s) and qs with 50% glycerin in a dropper bottle for sublingual administration.	3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	N/A	Gowns are not worn.	3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	N/A	Only garb is disposable gloves.	3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	N/A	Only garb is disposable gloves.	3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A	Goggles are not used.	3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes	There is designated space/large counter within the general pharmacy area but it is not a separate room.	4.1

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		Observation	Inspector Notes	USP Reference(s)
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Pharmacy uses La Crosse Alerts to electronically, continuously monitor temperature.	4.2

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		Observation	Inspector Notes	USP Reference(s)
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes	Data is downloaded every two weeks and kept for at least 5 years.	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	PIC calibrates the thermometer twice a year by bringing in another thermometer and checking against the temperature monitoring device in the pharmacy.	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		72.6°F.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	N/A	No equipment is used except syringes which are discarded.	4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		Lysol All Purpose cleaner and alcohol.	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	No		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	No	PIC stated all work surfaces are cleaned and sanitized at the beginning of each shift only.	5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes	Not visibly soiled yet.	5 Table 1

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15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	N/A	Pharmacy does not compound with API or any component that could generate airborne chemical particles. All non-sterile compounding is done using manufactured allergenic extracts in a 50% glycerin/50% distilled water vehicle.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes	Pharmacy does not compound with API or any component that could generate airborne chemical particles. All non-sterile compounding is done using manufactured allergenic extracts in a 50% glycerin/50% distilled water vehicle.	6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes	Each manufactured allergenic extract has its own syringe which is "washed" between uses. A new syringe for each allergenic extract is used every day.	6.1 Table 2

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18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes	Only equipment used is a syringe.	6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	N/A	Only equipment used is a syringe.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A	Only equipment used is a syringe.	6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	No		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	N/A		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	N/A		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	N/A		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	N/A		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	No	Pharmacy uses distilled water to compound the 50% glycerin vehicle.	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	Pharmacy mixes equal parts of glycerin with distilled water to make the vehicle for the sublingual allergy drops.	6.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	N/A	All allergenic extracts are manufactured. Pharmacy uses glycerin as a vehicle. Pharmacy obtains COA for glycerin.	6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A	All components have an expiration date.	6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4

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Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	No	There are no SDS in the pharmacy.	6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	No		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	No		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes	In the P&P.	6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes	USP 795. The sublingual allergy drops are considered topical because they are placed under the tongue and absorbed, not swallowed. The vehicle is 50% glycerin which is considered non-aqueous.	7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	N/A		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes	Visual inspection.	7.1

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Nonsterile Compounding Inspection for USP <795>

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e-Profile ID: 621474
Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes	Each compound is specific to the patient therefore the MF is used as the CR.	7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	N/A		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes	Visual inspection.	7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes	The MF is the CR because each compound is unique to each patient.	7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	Pharmacists observe the technicians compounding.	2, 7.2, 8

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
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Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	No	Label has Slit Solution with the number. The list of allergen extracts is provided on a supplemental sheet because they all would not fit on the immediate label. The average sublingual allergy drop compound has 15 allergenic extracts added but may be as high as 30. Allergenic extracts are various species of trees, plants, foods, and animals.	9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	N/A	All stored at controlled room temperature.	9

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		Observation	Inspector Notes	USP Reference(s)
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes	Label did state "Exp Date" but was changed to "Use By" during the inspection.	9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	N/A	No special handling needed.	9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes	Label did state "Exp Date" but was changed to "Use By" during the inspection.	10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes	PIC stated sublingual allergy drops are considered topical because they are placed under the tongue and absorbed. Allergy drops and allergenic extracts are not viable in the gut. The vehicle is 50% glycerin and 50% distilled water. FDA considers allergenic extracts in 50% glycerin to be stable and not be aqueous. Aqueous allergenic extracts do not use glycerin as a vehicle. BUD is 150 days. Pharmacy dispenses a three month supply.	10.4 Table 4 USP <659>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Allergychoices Inc. dba Allergychoices Pharmacy
e-Profile ID: 621474
Inspection Date: 12/20/2023

		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	Reviewed one complaint.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes	Written.	12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2

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		Observation	Inspector Notes	USP Reference(s)
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes	Based on the P&P.	12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes	Based on the P&P.	12.1
49.2	The pharmacy documented the implementation of the recall.	Yes	Based on the P&P.	12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes	Based on the P&P.	1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes	Based on the P&P.	12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes	Based on the P&P.	12.1

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		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes	Pharmacy seals the dropper bottle in a silver bag using Silver Seal Kapak. This is labeled and then placed in a USPS labeled box to mail to the patient.	13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	No accommodations.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2

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		Observation	Inspector Notes	USP Reference(s)
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes	Only garb is disposable gloves.	3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Sublingual allergy drop compound with seven different allergenic extracts including trees and plants, in a 50% glycerin/50% distilled water vehicle.	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1

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		Observation	Inspector Notes	USP Reference(s)
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	No	There are no SDS in the pharmacy.	6.2

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		Observation	Inspector Notes	USP Reference(s)
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes	Compounds are specific to each patient and cannot be anticipatorily compounded.	1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes	The MF is the CR because each compound is unique to each patient.	8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes	The MF is the CR because each compound is unique to each patient.	8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	N/A	All CNSP's are compounded then dispensed. None are stored for later dispensing.	8, 8.1

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		Observation	Inspector Notes	USP Reference(s)
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (e.g., long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**Pharmacist**	**Pharmacist**	**Pharmacist**	**Technician**	**Technician**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						Reviewed total of 3 RPh and 6 technicans - all findings were the same.
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist	Pharmacist	Pharmacist	Technician	Technician	Notes
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Missing	Missing	Missing	Missing	Missing	There are no SDS in the pharmacy.
1.12	The training record for spill management is complete.	Missing	Missing	Missing	Missing	Missing	No records on training of spill clean up.
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist	Pharmacist	Pharmacist	Technician	Technician	Notes
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Missing	Missing	Missing	Missing	Missing	There are no SDS in the pharmacy.
2.12	The annual competency assessment for spill management is complete.	Missing	Missing	Missing	Missing	Missing	No records on training of spill clean up.
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Missing	Missing	Missing	Missing	Missing	

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

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Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

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Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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Pharmacy Name: Allergychoices Pharmacy

Pharmacy Address: 2731 National Drive, Onalaska WI 54650

NABP Facility e-Profile ID: 621474

VPP Inspection Date: 12/20/2023

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	22	67.01	The pharmacy only produces compounded sublingual immunotherapy. The automated software is unable to complete a DUR due to the complex nature of the compounded entry. Pharmacists maunally complete a DUR for each prescription and are trained to check each required element to ensure patient safety. Expectations on what is included in a DUR is added to the SOP for prescription processing.	1/10/24	N	
Updates/New SOPs or P&Ps	30-31	1.0 & 1.5	The pharmacy has implimented a SOP on temperature monitoring. The pharmacy has always monitored temperature, there is now a formal SOP denoting the exact proceedures.	1/10/24		
Updates/New SOPs or P&Ps	35-36, 49, 68-69	3.0,3.2, 3.3, 26.2, 58.0 &58.8	The pharmacy has implimented a document to record training for spill clean up and SDS's. SOP were updated and training will be done annually to ensure competency.	1/10/24		
Updates/New SOPs or P&Ps	36	4.0	The Pharmacy has updated implimented documentation of designated person(s) evaluation of direct observation of compounding activities. This document contains SOP for observation and corrective action.	1/10/24		
Updates/New SOPs or P&Ps	37, 49	6.0, 6.3 & 26.1	SDS are available for hazardous chemicals inside the pharmacy. Garb requirements are based off of USP 795 and SDS in the pharmacy. The Pharmacy does not have raw chemical API's; the compounds are made from manufactured drugs. There are no Hazardous Substances in the pharmacy.	1/10/24		
Updates/New SOPs or P&Ps	42	15.0 & 15.2	Staff will clean all work surfaces at the beginning and end of the shift and document the cleaning.	1/10/24		
Updates/New SOPs or P&Ps	49	26.3	A spill clean up kit is available for use when needed	1/10/24	N	
Clarification or Further Explanation	54	31.0 & 31.4	[illegible] prescription sent listing each ingredient with quantity and strength as a supplement to the prescription label	1/10/24	N	

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This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Allergychoices Disciplinary Disclosure

Allergychoices, Inc. does not have any ongoing disciplinary actions. All historic actions that occurred under the prior/current owners have since been resolved.

1. *Wisconsin Pharmacy Examining Board (February 13, 2013):* On February 13, 2013, Allergychoices, Inc. ("Allergychoices"), under its prior ownership, entered into a Final Order and Stipulation with the Wisconsin Pharmacy Examining Board Concerning Allergychoices' practice of sending patient-specific compounded prescriptions to a physician's office for resale to the patient (the "Wisconsin Stipulation"). The Wisconsin Pharmacy Examining Board reprimanded Allergychoices' permit and imposed a $1,000 fine and $3,500 in costs, which Allergychoices promptly paid.

2. *Utah Board of Pharmacy (July 30, 2013):* On July 30, 2013, the Utah Board of Pharmacy reprimanded and fined Allergychoices $1,000 as a reciprocal action based on the Wisconsin Stipulation (the "Utah Action").

3. *Michigan Board of Pharmacy (March 14, 2014)*: Effective March 14, 2014, the Michigan Board of Pharmacy issued a Consent Order under which Allergychoices was reprimanded and fined $500 as a reciprocal action based on the Wisconsin Stipulation ("Michigan Consent Order").

4. *South Carolina State Board of Pharmacy (June 20, 2014):* Effective on or around June 20, 2024, Allergychoices entered into a Consent Agreement with the South Carolina State Board of Pharmacy under which Allergychoices was reprimanded as a reciprocal action to the Wisconsin Stipulation ("South Carolina Consent Agreement").

5. *Alabama State Board of Pharmacy (March 20, 2015):* Effective March 20, 2015, Allergychoices entered into a Consent Order with the Alabama State Board of Pharmacy under which Allergychoices was ordered to pay $1,000 as a reciprocal action based on the Wisconsin Stipulation, Michigan Consent Order, and South Carolina Consent Agreement ("Alabama Consent Order").

6. *Louisiana Board of Pharmacy (May 4, 2016):* Effective May 4, 2016, Allergychoices entered into a Consent Agreement with the Louisiana Board of Pharmacy under which Allergychoices was assessed a fine of $5,000 and $250 in costs for the failure to report the Alabama Consent Order on its 2016 Louisiana Renewal Application (the "Louisiana Consent Agreement").

7. *Texas State Board of Pharmacy (November 1, 2016):* Effective November 1, 2016, Allergychoices entered into an Agreed Board Order with the Texas State Board of Pharmacy under which Allergychoices Texas license was reprimanded as a reciprocal action based on the Louisiana Consent Agreement.

8. *Maryland State Board of Pharmacy (August 5, 2016):* Effective August 5, 2016, Allergychoices entered into a Pre-Charge Consent Order with the Maryland State Board of Pharmacy under which Allergychoices was fined $1,000 as a reciprocal action based on the Wisconsin Stipulation, Utah Action, Michigan Consent Order, South Carolina Consent Agreement, Alabama Consent Order, and Louisiana Consent Agreement.

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Writer's Direct Dial: 602-229-5432
E-Mail: Bailey.Walden@quarles.com

March 26, 2024

VIA UPS OVERNIGHT AND EMAIL TO CNALLY@PHARMACY.NV.GOV

Candy Nally
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Change of Ownership
Allergychoices, Inc. dba Allergychoices Pharmacy
License No.: PH02496

Dear Ms. Nally:

We are writing on behalf of Allergychoices, Inc. dba Allergychoices Pharmacy ("Allergychoices") in follow-up to the application we submitted February 27, 2024 (the "Original Application"). As stated in the Original Application, Allergychoices will be involved in a multi-step transaction which will ultimately result in a new entity, Noon & Freeman Co., holding the membership interests of Allergychoices (the "Transaction"). As part of the Transaction, Allergychoices will convert from a corporation to a limited liability company. The effective date of the Transaction was originally scheduled for March 29th, 2024. However, some of the steps required to complete the Transaction have been delayed for business purposes. As a result, the Transaction is now scheduled to close on **April 12th, 2024**.

If you have any questions or if you need additional information, please contact me at 602-229-5432 or Bailey.Walden@quarles.com. Thank you for your consideration in this matter.

Very truly yours,

Bailey Walden

Bailey Walden

QB\89119844.1

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E-Mail: Bailey.Walden@quarles.com

March 26, 2024

VIA UPS OVERNIGHT AND EMAIL TO CNALLY@PHARMACY.NV.GOV

Candy Nally
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Change of Ownership
Allergychoices, Inc. dba Allergychoices Pharmacy
License No.: PH02496

Dear Ms. Nally:

We are writing on behalf of Allergychoices, Inc. dba Allergychoices Pharmacy ("Allergychoices") in follow-up to the application we submitted February 27, 2024 (the "Original Application"). As stated in the Original Application, Allergychoices will be involved in a multi-step transaction which will ultimately result in a new entity, Noon & Freeman Co., holding the membership interests of Allergychoices (the "Transaction"). As part of the Transaction, Allergychoices will convert from a corporation to a limited liability company. The effective date of the Transaction was originally scheduled for March 29th, 2024. However, some of the steps required to complete the Transaction have been delayed for business purposes. As a result, the Transaction is now scheduled to close on **April 12th, 2024**.

If you have any questions or if you need additional information, please contact me at 602-229-5432 or Bailey.Walden@quarles.com. Thank you for your consideration in this matter.

Very truly yours,

Bailey Walden

Bailey Walden

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Writer's Direct Dial: 602-229-5432
E-Mail: Bailey.Walden@quarles.com

February 27, 2024

VIA UPS OVERNIGHT

Dave Wuest, Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: Notice of Transaction
Allergychoices, Inc.
License No.: PH02496

Dear Executive Secretary Wuest:

Please accept this letter as formal notice of an upcoming transaction involving **Allergychoices, Inc., the abovementioned licensee ("Allergychoices").** Allergychoices will be involved in a multi-step transaction which will ultimately result in a new entity, Noon & Freeman Co., holding the membership interests of Allergychoices (the "Transaction"). As part of the Transaction, Allergychoices will convert from a corporation to a limited liability company. The Transaction is anticipated to be completed on or about March 29th, 2024. The enclosed organizational chart shows the ownership structure before and after the Transaction.

It is important to note that Allergychoices' day-to-day operations, Pharmacist-in-Charge, federal tax identification number, NPI, NCDPD, and address will all remain the same.

Enclosed please find the application, required attachments and license fee to effectuate these changes. Should you have any questions or require additional information, please contact me at 602-229-5432 or Bailey.Walden@quarles.com. Thank you for your consideration.

Very truly yours,

Bailey Walden

Bailey Walden

Encls.

QB\88368045.1

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

4

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☑ Other: Central Fill	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☑ Other: Central Fill

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☐ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Albertsons Central Fill Pharmacy Phoenix

Physical Address: 6120 W. Buckeye Rd. Bld 3 Ste 2

City: Phoenix State: AZ Zip: 85043

Mailing Address (if different from physical address): 250 E. Parkcenter Blvd

City: Boise State: ID Zip: 83706

Telephone: 833-637-2889 Toll Free # (NAC 639.708, NRS 639.23286): 833-637-2889

Fax: 480-240-1063 Contact Email: rxlicenses@albertsons.com

Website: _____

Nevada Business License # (if applicable) NV19861018574

Supervising/Managing Pharmacist Name (NRS 639.220): Madeline Kaup

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24374

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Madeline Kaup	NV Pharmacist Registration #: 24374
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Safeway Inc.

Corporation Name: Safeway Inc.

Mailing Address: 250 E. Parkcenter Blvd

City: Boise State: ID Zip: 83706

Telephone: 208-395-6200 Email: rxlicenses@albertsons.com

Contact Person Name: Dawn Burrow License Specialist

Date of SEC Registration: See 10K	SEC Registration Number:	Stock Exchange Symbol: ACI

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☑ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the License Specialist (title) for Albertsons Central Fill Pharmacy Phoenix (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Dawn Burrow POA Attached

Print Name of Authorized Person

Dawn Burrow

Original signature of Authorized Person (copies or stamps not accepted)

OCT 28 2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Dawn Burrow hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the License Specialist (title) for Albertsons Central Fill Pharmacy Phoenix (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Dawn Burrow
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 30 day of OCTOBER, 2024

Beckie Maxie
Notary Public

BECKIE MAXIE
Comm. No. 20180334
NOTARY PUBLIC
Expires: 02/21/2030
STATE OF IDAHO

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dawn Burrow POA Attached

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Dawn Burrow

Original signature of Authorized Person (copies or stamps not accepted)

OCT 28 2024

Date

Board Use Only	Date Received: 10/31/24	Amount: $500-cc

AUTHORITY	REGISTRATION #	DATE OF INSPECTION (I), CITATION (C), OR ORDER (O)	CITATION / CASE NO.	FINE ($)	FINDINGS	DISCIPLINARY ACTION / RESTRICTION(S) ON REGISTRATION / IMPACTS	CURE ACTION(S) TAKEN
CA BOP	PHY 52140	01/28/24	CI 2021 94526	$ 50,000.00	From January 29th, 2022, to March 30th, 20222 a Vons Pharmacy District Manager sent emails to pharmacists, encouraging them to reach goals for administering immunizations, prescription transfers, and dispensing Flowflex COVID tests. The California Board of Pharmacy alleged that the emails violated the California Bus. & Prof. Code § 4113.7. which prohibits a chain pharmacy from establishing a quota related to the duties of a pharmacist or pharmacy technician. Vons paid a fine of $50,000 but did not admit to fault.	Fine imposed.	Fine paid
CA BOP	PHY51373	n/a	CI2021 96010	$5,000	Call sheets in October and November of 2022 failed to show that another staff member was present to assist the pharmacists on duty. Violation of CCR Title 16:1714.3(a)(1)	Fine imposed.	Fine paid

Store ID	Owner	Street Address	Registration #	Effective Date(s)	Case No(s).	Summary	Probation End Date	Agency
SWY 782	Safeway Inc.	7601 Hwy 26, Sandy, OR 970	RP-0000978	5/3/2022	2022-0591	From 2/12/2022 to 2/20/2022, SWY #782 failed to maintain temperature logs for the medicatin refridgerator, "RX Cooler #1". On 2/20/2022, Rx Cooler #1 reached a temperature outside of USP or FDA guidelines, and facility failed to document the decision to quarantine drugs for destruction or determine which drugs were safe for use. Additionally, the pharmacy continued to use the drugs exposed to the temperature excursion. On 5/15/2022, the pharmacy's "Rx Cooler #2" also failed to maintain proper temperatures and the registrant did not document the decision to quarantine drugs for destruction or determine which drugs were safe for use. Additionally, the pharmacy continued to use the drugs exposed to the temperature excursion. The OR BOP propsed a $10,000 fine on 5/3/2024 and no similar violation shall occur within 3 years. A Quality Assurance Plan shall be implemented to correct the violations and document retraining of all current and future pharmacy staff for 12 months.	N/A	OR BOP
SWY 4381	Safeway Inc.	1205 Campbell St., Baker City OR 97814	RP -0000890	03/01/23	2022-0150	On January 25, 2022, a patient received a text reminding them to refill their prescription. Patient confirmed the refill request, and the pharmacy provided the patient with a date upon which the prescription would be ready. The prescription was not ready on that date resulting in the patient receiving a partial fill. The Board concluded that the pharmacy's misrepresentation to the patient about when the prescription would be ready constituted unprofessional conduct and was grounds for discipline and was fined $1,000.	N/A	OR BOP
SWY 3410	Safeway Inc.	30 College Rd., Fairbanks, AK 99701	178587	05/23/23	2022-000905	Safeway Pharmacy #3410 received notification on 05/10/23 from the Alaska Board of Pharmacy that it was discovered that the pharmacy failed to file the pharmacist-in-charge application within the 10 day required time frame. Safeway Pharmacy #3410 was ordered to pay a fine in the amount of $500. There are no restrictions being placed on the pharmacy's registration that would affect its ability to operate as a pharmacy in the State of Alaska. No other Safeway pharmacy registrations are impacted by this settlement. The Consent Order is currently pending execution.	N/A	AK BOP
SWY 1267	Safeway Inc.	6460 E Yale Ave. Unit F, Denver, CO 80222	PDO.0000000188	01/05/24	2023-9480	On December 08, 2023 during a routine inspection it was discovered that the pharmacy failed to file a PIC change application. SWY #1267 failed to submit the application within the 30 day timeframe and agreed to pay a $1,150 fine. There are no restrictions placed on the pharmacy's registration that would affect its ability to operate as a pharmacy in the State of Colorado.	N/A	CO BOP

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SAFEWAY INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2096948 8300

SR# 20243645291

Authentication: 204353726

Date: 09-10-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :
Y009706

AZ Permit Exp.Date :
10/31/2025

Business Name :
Albertsons Central Fill Pharmacy Phoenix

Address :
6120 W. Buckeye Rd. Bld 3

Zip :
85043

City :
Phoenix

State :
AZ

Phone :
(480) 240-1033

Email :
MKaup07@Safeway.com

Inspection Date :
07/19/2024

PIC :
Madeline Kaup

Pic License Exp Date :
10/31/2024

Inspection Reviewed With :
Madeline Kaup

Reviewers License# :
S024160

Inspection type :
Opening

Inspection Conducted By :
Steve Haiber , Ram Karlapudi

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

Licensed Beds

DHS License #

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☑ S ☐ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(D)
7	Enclosed (barrier)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(H)

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12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

SECURITY

1	Controlled substances	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

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3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)
6	Policy and procedure manual-pharmacy operations	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)
8	Policy and procedure manual-automation	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04

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9	Policy and procedure manual-compounding	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410; R4-23-670
10	Arizona statutes/rules	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Current antidote/drug interaction information	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408
4	Computer-patient profiles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(C)(4)

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7	Prescription label ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C) Reminder: Need to include Albertsons Central Fill Pharmacy Phoenix (Y009706) on the Rx label.	☑ S	☐ C/P	☐ U	☐ N/A
8	Federal transfer labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)	☐ S	☐ C/P	☐ U	☑ N/A
9	Warning labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)	☑ S	☐ C/P	☐ U	☐ N/A
10	Written patient information R4-23-402(C)(4); R4-23-402(I)	☑ S	☐ C/P	☐ U	☐ N/A
11	Consultation log R4-23-402(G)	☑ S	☐ C/P	☐ U	☐ N/A
12	Federal medication guides 21 CFR part 208	☑ S	☐ C/P	☐ U	☐ N/A
13	Hospital IV label R4-23-658	☐ S	☐ C/P	☐ U	☑ N/A
14	Generic Rx blanks R4-23-402(A); R4-23-407(D)	☑ S	☐ C/P	☐ U	☐ N/A
15	Immunization administration recordkeeping R4-23-411(F)	☐ S	☐ C/P	☐ U	☑ N/A
16	Schedule V register R4-23-612(A)(2)	☐ S	☐ C/P	☐ U	☑ N/A
17	Methamphetamine precursor sales log ARS 32-1977	☐ S	☐ C/P	☐ U	☑ N/A

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18	Red C stamp	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-502
20	Graduates	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)

29	Mechanical storage and counting device	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-615
30	Mechanical counting device	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Hours of operation: Sun - Thurs: 6.30 am - 11.00 pm.

Reminder: Need to include Albertsons Central Fill Pharmacy Phoenix (Y009706) on the Rx label.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 11/27/2023
Receipt Number: 2023169656
Receipt Amount $: 480.00

Pharmacy - Chain

PERMIT NO
Y009706

EXPIRES
10/31/2025

Issued to :

Albertsons Central Fill Pharmacy Phoenix
Safeway Inc.
250 E. PARKCENTER BLVD
BOISE, ID 83706

Albertsons Central Fill Pharmacy Phoenix
6120 W. BUCKEYE RD. BLD 3 STE 2
PHOENIX, AZ 85043

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Safeway Inc.
LICENSE NUMBER : Y009706
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

• Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
• You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

• Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
• In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
• Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Albertsons Central Fill Pharmacy Phoenix
Address :	6120 W. Buckeye Rd. Bld 3 Ste 2 Phoenix AZ 85043
Registration No :	Y009706
Permit Type :	Pharmacy
Sub Type :	Chain
Date Issued :	07/20/2024
Expiration Date :	10/31/2025
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 10/30/2024

Updated 5/2023

OWNERSHIP/CONTROL DISCLOSURE DOCUMENT

3787

SAFEWAY INC.
State of Domicile: Delaware
File No. 2096948
Formation Date: 7/23/1986
FEIN: 94-3019135
Address: 11555 Dublin Canyon Road, Pleasanton, CA 94588
Phone: (800) 723-3929

OFFICERS/DIRECTORS

FULL NAME	TITLE	EFFECTIVE	BUSINESS ADDRESS
(Muhammad) Omer Gajial	Executive Vice President, Pharmacy & Health	9/7/2020	250 E. Parkcenter Boulevard Boise, ID 83706
Robert Larson	Senior Vice President & Chief Accounting Officer	2/22/2016	250 E. Parkcenter Boulevard Boise, ID 83706
Cody Perdue	Vice President, Treasurer & Assistant Secretary	12/3/2021	250 E. Parkcenter Boulevard Boise, ID 83706
Bradley Reed Beckstrom	Secretary	4/28/2023	250 E. Parkcenter Boulevard Boise, ID 83706

OWNERSHIP INFORMATION

OWNER	5% OR GREATER OWNERSHIP INTEREST	FEIN	BUSINESS ADDRESS	PHONE
Albertsons Safeway LLC	**100%** Owner of Safeway Inc.	86-3915481	250 E. Parkcenter Boulevard Boise, ID 83706	(208) 395-6200
Albertsons Companies, Inc.	**100%** Owner of Albertsons Safeway LLC	47-4376911	250 E. Parkcenter Boulevard Boise, ID 83706	(208) 395-6200

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended February 24, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39350



Albertsons Companies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-4376911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

250 Parkcenter Blvd.
Boise, Idaho, 83706

(Address of principal executive offices and zip code)

(208) 395-6200

(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.01 par value	ACI	New York Stock Exchange

Securities registered under Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 02836		☐ Hospital
			☒ Other: specialty / Hemophilia

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Drugco Health (DPP Pharmacy (NC)

Physical Address: 107 Smith Church Rd. Suite A

City: Roanoke Rapids State: NC Zip: 27870

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 866-601-8434 Toll Free # (NAC 639.708, NRS 639.23286): 866-601-8434

Fax: 866-601-8434 Contact Email: drew@drugcopharmacy.com

Website: www.drugcohealth.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Chandler Huggins

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22019

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Andrew Huggins	NV Pharmacist Registration #: 22019
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	X	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Andrew Chandler Huggins	Credentials: PharmD	%: 50%
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: North Carolina

Parent Company (if any): _____

Corporation/Organization Name: DDP Pharmacy INC

Mailing Address: 107 Smith Church Rd

City: Roanoke Rapids State: NC Zip: 27870

Telephone: 828-612-2785 Email: drew@drugcopharmacy.com

Contact Person Name: Andrew Huggins

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Huggins

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/30/24

Date

Board Use Only	Date Received: 10/3/24	Amount: $500-ck 50155

STATE OF NORTH CAROLINA
COUNTY OF HALIFAX

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
09 POB 6554

NORTH CAROLINA BOARD OF PHARMACY,

Petitioner,

v.

DRUGCO DISCOUNT PHARMACY,

Respondent.

CONSENT ORDER

FINDINGS OF FACT

1. At all relevant times, Drugco Discount Pharmacy ("Drugco") was the holder of North Carolina Board of Pharmacy Permit Number 05053 and is located in Roanoke Rapids, North Carolina. Drugco operates two other store locations not involved in this matter.

2. Drugco's Roanoke Rapids store fills approximately 1,400 prescriptions daily, and it is located adjacent to a hospital and other large medical offices.

3. A controlled substances audit completed by the North Carolina Board of Pharmacy ("the Board") on March 10, 2009, revealed that, at that time, Drugco was missing approximately 136,000 dosage units of various controlled substances. Those substances included Viagra, Lortab, Glucotrol, Trazodone, Phenergan, Nexium, Alprazolam (generic Xanax), Hydrocodone (generic Lortab), and Fioricet.

4. Four Drugco employees diverted the missing controlled substances. Those employees were RPh. Timothy Bratton and Technicians Mary Frazier, LaToya Pierce, and Anna Vann. RPh. Bratton, Drugco's pharmacist-manager, provided medications without prescriptions on multiple occasions to at least four different patients. The Board summarily suspended RPh. Bratton's pharmacy license on April 8, 2009 and he subsequently surrendered his license.

5. Following the Board's controlled substances audit, Drugco put the following security measures in place beginning in April 2009:

a. Drugco engaged the former Chief of Police of the Roanoke Rapids Police Department as its Security Advisor. The Security Advisor is responsible for proactively addressing risks and overseeing all aspects of security at all three Drugco locations. This security includes protecting against internal and external thefts and diversions.

b. Drugco has implemented an extensive pre-employment application, screening, and background check process for all pharmacy and retail employees. The employment application includes prior employment, personal and professional references, copies of appropriate documentation, authorization release forms and consent to drug and alcohol testing.

c. The Security Advisor conducts interviews with applications and provides recommendations for hiring decisions based on the information collected.

d. Background investigations are conducted on potential employees for all pharmacy and retail staff. These include multi-state criminal records checks, social security and employment verification, driver's license history, and sex offender registry.

e. All offers of employment are conditional offers that are subject to passing pre-employment drug screening.

f. Drugco adopted a formal drug and alcohol policy. All Drugco employees are subject to and must agree to random drug testing.

g. Employee lockers were installed and no personal packages or purses are allowed in the workplace. Drugco also has implemented random purse and package

security checks for all employees. Pockets have been removed or sewn closed on all pharmacy staff work smocks.

h. Drugco now has an in-service training program targeted at security and diversion issues. This program includes at least semi-annual drug diversion intervention training with pharmacy staff, as well as programs on fraud, larceny, robbery and workplace dishonesty.

i. Drugco has implemented standardized incident reporting that requires documentation of all incidents concerning criminal behavior, medical emergencies and personal injury to proactively identify and track recurring problems.

j. Drugco now utilizes perpetual inventory software. This perpetual inventory is monitored on a regular basis and results are provided to and reviewed by Drugco's owner, by the pharmacy manager, and by the Security Advisor. The prescription inventory software is password protected and any changes or modifications to that software can be tracked to the individual accessing the software. It is not possible for the inventory software to be modified without indicating what password was utilized in making such changes or modifications.

k. Drugco now conducts regular pharmacy register audits and validates that the prescriptions filled match the prescriptions sold at the register.

l. All deliveries of pharmaceuticals are inventoried upon receipt and immediately stocked or appropriately secured within the pharmacy.

m. Drugco obtains a monthly report of all controlled drug purchases through North Carolina Mutual Drug. This report is independent of the individual delivery

inventories. This monthly report is compared to and audited with the inventory received for all three Drugco locations.

n. Drugco has strengthened internal controls for controlled substances that have been damaged.

o. Drugco purchased and installed a digital camera surveillance system. This surveillance system enables Drugco's Security Advisor to randomly monitor various locations within each pharmacy and keeps a video recording for 30 days, which recordings can be reviewed if a diversion, theft or other problem is suspected or determined.

p. Drugco has installed an alarm system to deter or prevent external thefts.

q. Drugco installed a peep-hole in the stockroom delivery door.

CONCLUSIONS OF LAW

1. Drugco violated N.C. Gen. Stat. §§ 90-85.38 (a)(6) and (b) and 21 N.C. Admin. Code 46.1805.

2. The conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under N.C. Gen. Stat. § 90-85.38.

Based on the foregoing:

1. Permit Number 05053 is hereby SUSPENDED for a period of five (5) days. This suspension is hereby STAYED for a period of one (1) year, provided that Drugco complies with the following conditions:

a. Drugco shall continue to maintain the changes to its monitoring, security, and record-keeping systems that it put in place following the events described in the Board's petition or substantially similar measures;

b. Drugco shall be subject to an unannounced inspection by the Board staff to confirm that Drugco continues to maintain the monitoring and record-keeping systems discussed above;

c. Drugco shall be subject to an unannounced controlled substances audit by the Board staff;

d. Drugco shall violate no laws governing the practice of pharmacy or the distribution of drugs;

e. Drugco shall violate no rules and regulations of the Board; and

f. Drugco shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation and compliance with the provisions of this Consent Order.

If Drugco fails to comply with the terms or conditions of this Order, the period of stay described above shall be lifted and Drugco may be subject to additional disciplinary action by the Board.

Dated: 3-17-2010

On behalf of Drugco Discount Pharmacy

Sworn to and subscribed before me on
this 17 day of March, 2010.

Notary Public

Comm exp: 7-20-2014

Dated: 3-17-2010

Jay W. Campbell, IV
Executive Director
North Carolina Board of Pharmacy

EXPLANATION OF FACTS

Drugco Health - Specialty Pharmacy (**NC Permit #: 11032**), the entity applying for out-of-state pharmacy permit, is a wholly owned subsidiary of DDP Pharmacy INC. The specialty pharmacy operates independently of all other subsidiaries of DDP Pharmacy INC including the home health division and retail pharmacy division, and was first opened for business in **April 2011**.

In **March 2009** Drugco Discount Pharmacy (**NC Permit #: 05053**), the retail pharmacy division of DDP Pharmacy INC, was given disciplinary action due to the diversion of controlled substances by multiple employees. The diversion was not noted quickly due to the fact that one of the participants was the PIC of the retail division. This individual never had a corporate officer role or ownership stake in any division of DDP Pharmacy INC. This disciplinary action also occurred over 2 years prior to the opening of Drugco Health - Specialty Pharmacy.

I noted this disciplinary action of the retail pharmacy division on this application simply due to the fact that both permits are owned by the same North Carolina corporation. Both permits operate independently, and **the permit Drugco Health - Specialty Pharmacy, has never had any disciplinary action imposed upon it.** I am also the PIC for Drugco Health - Specialty Pharmacy, and my pharmacist license is also clear of any disciplinary actions.

Please let me know if you need further information beyond what is listed here. Thank you again for taking the time to work with us.

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

Co-Owner | PIC |

1. I am the Chief Executive Officer (title) for Drugco Health (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Andrew Huggins

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/30/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Andrew Chandler Huggins hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the co-owner/ PIC/ Chief Executive Officer (title) for Drugco Health (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 30th day of September, 20 24

Notary Public

SHERI B. RIGHTMYER
NOTARY PUBLIC
EXPIRES DECEMBER 10, 2024
STATE OF NORTH CAROLINA

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

DDP PHARMACY, INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 28th day of October, 1988, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 8th day of October, 2024.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 121200373-1 Reference# 21931033- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

Inspection Details

Name	Drugco Health	**Case #**	n/a	**Permit**	11032
Address	107 Smith Church Rd., Suite A Roanoke Rapids, NC 27870	**Person Providing Info**	Andrew Huggins	**Inspection Date**	03/06/2023
		Person In Charge	Andrew Chandler Huggins	**Inspection User**	Frederick, Lindsey
# RPhs	2	**Rx Volume/Date**	15	**Inspection District**	DISTRICT4
# Techs	1	**Hours**	M-F 8:30-5:30pm, 24/7 clinical coverage		
Follow-Up CAP	No				
CAP Requested	No				
CAP Documentation Received	No	**Office**	No		
		Commercial Use	No		
Additional Documents	Yes	**Ship to Other States**	Yes		
Non-Sterile Compounding Levels		**States Shipped To**	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, DC, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming		
Sterile Compounding Levels					

Pharmacy Staffing

What is the P:T ratio at the time of inspection: 1:2

How often is there only one pharmacist on duty: Always

If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift:
n/a

How many technicians are usually on shift at a time: 1

What is the approved Pharmacist: Technician ratio?

Are pharmacists asked to do any duties outside of the pharmacy :
No

Pharmacy Volume

Does pharmacy administer vaccines: No

Does pharmacy conduct any point of care testing such as COVID:
No

What is the daily average of vaccines:

What staff members are administering vaccines and what type of vaccines:

What is the daily average of testing:

How far behind is the pharmacy on filling and verifying prescriptions:
not behind

How long has this backlog persisted: n/a

What staff is responsible for administering test and what is testing procedure:

Are administered vaccines reported to the appropriate vaccine registry:

In your opinion, does the rate you are dispensing per hour or per day pose a threat to public health and safety:
No

Comments

This inspection was requested by PM Huggins because he needed a current inspection for an out of state permit.

The pharmacy orders medications through McKesson, NC Mutual, Sanofi and Cardinal.

The pharmacy has approximately twenty (20) sales reps/marketers throughout the US.

Pharmacy uses FedEx to ship everything and refrigerated medications are overnighted and two day deliveries for nonrefrigerated medications.

Pharmacy bills most insurances and most medications require prior authorization. PM stated that they occasionally use manufacturer coupons.

Pharmacy has out of state permits in 48 states.

Pharmacy mostly orders hemophilia drugs.

General Pharmacy Regulations

	Answer	Question
1)	Satisfactory	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2)	Satisfactory	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
	Comments: 1:2 observed (1 intern)	
3)	Satisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
4)	Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5)	Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
	Comments: (b) Medication Incident and Discrepancy Report Form, no recent errors	
6)	Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
7)	Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8)	Satisfactory	NCGS 90-85.47 - Quality Assurance Program
9)	Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
10)	Not Applicable	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
11)	Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
12)	Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
13)	Not Applicable	NCGS 90-640 (b) - ID badge
	Comments: closed door facility	
14)	Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
15)	Satisfactory	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)

General Pharmacy Regulations

	Answer	Question
	Comments: Advised PM to add RPh's name, it has the name of the person who input the prescription	
16)	Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
	Comments: (e) signed while on site	
17)	Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
18)	Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
19)	Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
20)	Unsatisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
21)	Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
22)	Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
23)	Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
	Comments: (7) Up to date	
24)	Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
25)	Satisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
26)	Satisfactory	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
	Comments: Counseling provided via phone and periodic reviews with patients (g) documented on form	
27)	Satisfactory	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
	Comments: Returned to Return Solutions	
28)	Satisfactory	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
29)	Not Applicable	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
30)	Not Applicable	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
31)	Not Applicable	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
32)	Not Applicable	21CFR 1305.05 (a) - power of attorney on file at registered location.
33)	Not Applicable	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
34)	Not Applicable	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
35)	Not Applicable	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
36)	Not Applicable	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each

General Pharmacy Regulations

	Answer	Question
		unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
37)	Not Applicable	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
38)	Not Applicable	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner.
39)	Not Applicable	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
40)	Not Applicable	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
41)	Not Applicable	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
42)	Not Applicable	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
43)	Not Applicable	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
44)	Not Applicable	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
45)	Not Applicable	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
46)	Not Applicable	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
47)	Not Applicable	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

NORTH CAROLINA BOARD OF PHARMACY

Facility: Drugco Health
Address: 107 Smith Church Rd., Suite A Roanoke Rapids, NC 27870
Permit Type: Pharmacy
Permit #: 11032
Re-Issue Date: 11/01/2023
Expiration Date: 12/31/2024
Pharmacy Manager: Andrew Chandler Huggins (#20326)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 11032

NORTH CAROLINA BOARD OF PHARMACY

2024 Pharmacy

This is to certify that

DDP Pharmacy INC

doing business as

Drugco Health

107 Smith Church Rd., Suite A Roanoke Rapids, NC 27870

Has been renewed for the year ending December 31st 2024, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Andrew Chandler Huggins (#20326)

11/01/2023
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

NORTH CAROLINA BOARD OF PHARMACY

Licensee: Andrew Chandler Huggins
License Type: Pharmacist
License #: 20326
Re-Issue Date: 11/01/2023
Expiration Date: 12/31/2024

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

License #: 20326

NORTH CAROLINA BOARD OF PHARMACY

2024

Pharmacist

This is to certify that

Andrew Chandler Huggins

Is registered and entitled to practice as a Pharmacist as authorized under the North Carolina Pharmacy Practice Act for the year ending December 31st, 2024. This certificate is revocable for the causes specified in the law and must be conspicuously displayed in the pharmacy where holder practices.

IN WITNESS WHEREOF, The President and Executive Director Hereunto Affix Their Signatures

PRESIDENT

11/01/2023
Re-Issued

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

Ownership of DDP Pharmacy INC
Effective 11/1/2024

Andrew Chandler Huggins

Title: CEO/Co-Owner

Home Address: [redacted] Raleigh, NC [redacted]

Business Address: 107 Smith Church Rd, Roanoke Rapids, NC 27870

Registered Pharmacist Number: NC20326

[redacted]

Ownership Percentage: 50%

Frank Neal White

Title: CFO/Co-Owner

Home Address: [redacted] Raleigh, NC [redacted]

Business Address: 1096 East 10th St, Roanoke Rapids, NC 27870

[redacted]

Ownership Percentage: 50%

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD2614700	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-18-2023

DRUGCO HEALTH
107 SMITH CHURCH RD.
SUITE A
ROANOKE RAPIDS, NC 27870

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD2614700	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-18-2023

DRUGCO HEALTH
107 SMITH CHURCH RD.
SUITE A
ROANOKE RAPIDS, NC 27870

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended provide that the Attorney General may revoke or suspend a registration to manufacture, distribute dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: DDP Pharmacy INC (DBA: Drugco Health)

Pharmacy/Wholesaler License # (if applicable): PH02836

Physical Address: 107 Smith Church Rd, Suite A

City: Roanoke Rapids State: NC Zip: 27870

Mailing Address (if different from physical address): Same as physical

City: State: Zip:

Telephone: 866-601-8434 Website: www.drugcohealth.com

Licensing Company Email: N/A

Section 2: Personal Information

First: Andrew Middle: Chandler Last: Huggins

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Raleigh State: NC Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Newton-Conover High School		08/99 - 05/2003	
Address	**City**	**State**	**Zip**
338 W 15th St	Newton	NC	28658
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Furman University		08/03 - 05/04	
Address	**City**	**State**	**Zip**
3300 Poinsett Highway	Greenville	SC	29613
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina at Charlotte		05/04 - 05/05	
Address	**City**	**State**	**Zip**
9201 University City Blvd	Charlotte	NC	28223
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
UNC Eshelman School of Pharmacy			
Address	**City**	**State**	**Zip**
301 Pharmacy Lane	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Bachelor of Science (Pharmaceutical Sciences) and Doctor of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2017 - Current	[redacted]	Raleigh	NC	[redacted]
05/2012 - 05/2017		Raleigh	NC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
DDP Pharmacy INC (DBA: Drugco Pharmacies)			06/09 - Current	
Business Address		**City**	**State**	**Zip**
107 Smith Church Rd		Roanoke Rapids	NC	27870
Phone	**Title**		**Number of Employed Hours**	
252-537-7010	Pharmacist (06/09 - 06/12), COO (06/12-05/20), CEO		>30,000	
Description of Duties				
Served in multiple capacities including as a pharmacist and executive.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Andrew Huggins, **certify that as the designated representative for**

DDP Pharmacy INC (DBA: Drugco Health),

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ACH I am at least 21 years of age;
3. ACH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ACH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ACH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ACH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ACH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andrew Huggins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/30/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Huggins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/30/2024

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Halifax

I, Andrew Huggins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/30/24

Date

Subscribed and Sworn to before me this 30th day of September, 2024

Notary Public Signature

SHERI B. RIGHTMYER

NOTARY PUBLIC
EXPIRES DECEMBER 10, 2024
STATE OF NORTH CAROLINA

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler DDP Pharmacy INC (DBA: Drugco Health)

Physical Address 107 Smith Church Rd, Suite A

City Roanoke Rapids State NC Zip 27870

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone 866-601-8434 Website www.drugcohealth.com

Licensing Company Email drew@drugcopharmacy.com

Section 2: Personal Information

First Andrew Middle Chandler Last Huggins

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted]

City Raleigh State NC Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials ACH

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNC Eshelman School of Pharmacy		08/05 - 06/09	
Address	**City**	**State**	**Zip**
301 Pharmacy Lane	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Bachelor of Science (Pharmaceutical Sciences) and Doctor of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina Charlotte			
Address	**City**	**State**	**Zip**
9201 University City Blvd	Charlotte	NC	28223
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Furman University			
Address	**City**	**State**	**Zip**
3300 Poinsett Highway	Greenville	SC	29613
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Newton-Conover High School			
Address	**City**	**State**	**Zip**
338 West 15th St	Newton	NC	28658
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2017 - Current	[redacted]	Raleigh	NC	[redacted]
05/2012 - 05/2017	[redacted]	Raleigh	NC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials ACH

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
DDP Pharmacy, Inc.			06/09 - Current
Business Address	**City**	**State**	**Zip**
107 Smith Church Rd	Roanoke Rapids	NC	27870
Phone	**Title**		
252-537-7010	CEO		
Description of Duties			
Management of an independently owned chain of pharmacies and specialty pharmacy			

Business Name			From - To (MM/YY – MM/YY)
WH Pharmacy 1, LLC			08/18 - Current
Business Address	**City**	**State**	**Zip**
107 Smith Church Rd	Roanoke Rapids	NC	27870
Phone	**Title**		
252-823-7030	Member		
Description of Duties			
Owner of retail pharmacy			

Business Name			From - To (MM/YY – MM/YY)
WH Pharmacy 2, LLC			10/22 - Current
Business Address	**City**	**State**	**Zip**
107 Smith Church Rd	Roanoke Rapids	NC	27870
Phone	**Title**		
910-892-1176	Member		
Description of Duties			
Owner of retail pharmacy			

Business Name			From - To (MM/YY – MM/YY)
NC Pharmacy Group, LLC			03/14 - Current
Business Address	**City**	**State**	**Zip**
107 Smith Church Rd	Roanoke Rapids	NC	27870
Phone	**Title**		
252-519-1144	Member		
Description of Duties			
Owner of Retail Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Huggins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/30/2024

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Halifax

I, Andrew Huggins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/30/24

Date

Subscribed and Sworn to before me this 30th day of September, 2024

Notary Public Signature

SHERI B. RIGHTMYER

NOTARY PUBLIC
EXPIRES DECEMBER 10, 2024
STATE OF NORTH CAROLINA (Seal)

Applicant's initials ACH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler DDP Pharmacy, Inc.

Physical Address 107 Smith Church Road

City Roanoke Rapids State NC Zip 27870

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 252-537-7010 Website www.drugcohealth.com

Licensing Company Email drew@drugcopharmacy.com

Section 2: Personal Information

First Frank Middle Neal Last White

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Raleigh State NC Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials FNW

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwestern University Kellogg School of Management		08/04-06/06	
Address	**City**	**State**	**Zip**
2211 N Campus Drive	Evanston	IL	60208
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina at Chapel Hill		08/97-05/01	
Address	**City**	**State**	**Zip**
SASB North, CB# 2100	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Bachelors of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Roanoke Rapids High School		08/93-05/97	
Address	**City**	**State**	**Zip**
800 Hamilton Street	Roanoke Rapids	NC	27870
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18-present	[redacted]	Raleigh	NC	[redacted]
07/14-03/18		Raleigh	NC	

Applicant's initials FNW

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
DDP Pharmacy, Inc.			06/16-Present
Business Address	**City**	**State**	**Zip**
107 Smith Church Road	Roanoke Rapids	NC	27870
Phone	**Title**		
252-537-7010	Chief Financial Officer		

Description of Duties

Manage finances, accounting and human resources for specialty and retail pharmacy business.

Business Name			From - To (MM/YY – MM/YY)
WH Pharmacy 1, LLC			08/18-Present
Business Address	**City**	**State**	**Zip**
107 Smith Church Road	Roanoke Rapids	NC	27870
Phone	**Title**		
252-823-7030	Member		

Description of Duties

Owner of retail pharmacy.

Business Name			From - To (MM/YY – MM/YY)
WH Pharmacy 2, LLC			10/22-Present
Business Address	**City**	**State**	**Zip**
107 Smith Church Road	Roanoke Rapids	NC	27870
Phone	**Title**		
910-892-1176	Member		

Description of Duties

Owner of retail pharmacy.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Frank White

Print Name (First, Last)

Frank Neal White — 10/1/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Halifax

I, Frank Neal White, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Frank Neal White — 10/1/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 1st day of October 2024

SHB Rightmyer

Notary Public Signature

SHERI B. RIGHTMYER
NOTARY PUBLIC
EXPIRES DECEMBER 10, 2024
STATE OF NORTH CAROLINA

(Seal)

Applicant's initials FNW

STATE OF NORTH CAROLINA

NEW HANOVER County _____ Seat of Court

File No. 20CR707215

In The General Court Of Justice ☒ District ☐ Superior Court Division

(NOTE: This form should be used for only one DWI conviction. Multiple convictions sentenced under G.S. 20-179 may not be consolidated for judgment.)

STATE VERSUS

Name Of Defendant: FRANK NEAL WHITE

Race: W | Sex: M | [redacted] | State: NC | [redacted]

Date Of Offense: 7/6/2020

Attorney For State | ☐ Def. Found Not Indigent ☐ Def. Waived Attorney | Attorney For Defendant: JL ALLARD JR | ☐ Appointed ☒ Retained | Crt Rptr Initials

IMPAIRED DRIVING - JUDGMENT SUSPENDING SENTENCE

(For Offenses Committed On Or After Dec. 1, 2016)

☐ COMMITMENT ON SPECIAL PROBATION G.S. 20-179

Offense: ☒ Impaired Driving (G.S. 20-138.1). ☐ Impaired Driving in a commercial vehicle (G.S. 20-138.2). ☐ Operating a commercial vehicle after consuming alcohol and this was the defendant's second or subsequent conviction of this offense (G.S. 20-138.2A). ☐ Operating a school bus, school activity bus, child care vehicle, ambulance, other EMS vehicle, firefighting vehicle, or law enforcement vehicle after consuming alcohol and this was the defendant's second or subsequent conviction of this offense (G.S. 20-138.2B).

The defendant was found guilty/responsible, pursuant to ☒ plea ☐ pursuant to *Alford*) ☐ of no contest) ☐ trial by judge, ☐ trial by jury, of the offense specified above. The Court, based upon the determinations shown on the attached Determination of Sentencing Factors form (AOC-CR-311, Rev. 12/15), has imposed the following punishment level.

☐ Aggravated Level One. ☐ Level One. ☐ Level Two. ☒ Level Three. ☐ Level Four. ☐ Level Five.

The Court, having considered evidence, arguments of counsel and statement of defendant, ORDERS that defendant be imprisoned

for a minimum term of	for a maximum term of	In the custody of the Misdemeanant Confinement Program.
6 MONTHS	6 MONTHS	

☐ This sentence shall run at the expiration of sentence imposed in file number _____

The defendant shall be given credit for _____ days spent in confinement prior to the date of this Judgment as a result of this charge ☐ and as an inpatient at a facility operated or licensed by the State for the treatment of alcoholism or substance abuse after the commission of the above offense. Credit shall be applied against the ☐ minimum and maximum terms above. ☐ imprisonment for special probation below. (NOTE: *No credit may be given for the first 24 hours spent in confinement.*)

SUSPENSION OF SENTENCE

Subject to the conditions set out below, the execution of this sentence is suspended and the defendant is placed on

☒ unsupervised probation for 18 months.

☐ supervised probation for _____ months, the Court having received evidence and having found as a fact that supervision is necessary.

SPECIAL PROBATION - G.S. 15A-1351

☐ A. As a condition of special probation, the defendant shall serve an active term of _____ ☐ days ☐ months ☐ hours

☐ 1. in the custody of the Sheriff of this County. ☐ and pay jail fees.

☐ 2. as an inpatient in *(name treatment facility)* _____, shall follow the rules of that facility until discharged, and shall not leave its premises except as authorized under those rules.

NOTE: *This term shall NOT be reduced by good time, gain time, or parole, or, unless provided above, by jail or treatment time.*

☐ B. The defendant shall report in a sober condition to begin serving this term on: Day _____ Date _____ Hour _____ ☐ AM ☐ PM and shall remain in custody until: Day _____ Date _____ Hour _____ ☐ AM ☐ PM

☐ C. The defendant shall again report in a sober condition to continue serving this term on the same day of the week for the next 60 consecutive weeks, and shall remain in custody during the same hours each week until completion of the active term ordered.

☐ D. This term shall be served at the direction of the probation officer within _____ ☐ days ☒ months of this Judgment.

☐ E. Work release is recommended. ☐ F. Substance abuse treatment is recommended.

MONETARY CONDITIONS

The defendant shall pay to the Clerk of Superior Court the "Total Amount Due" shown below, plus the probation supervision fee if placed on supervised probation above, pursuant to a schedule ☐ determined by the probation officer, ☒ set out by the court as follows: _____

Costs	Fine	Restitution*	Attorney's Fees	Community Service Fee	EHA Fee/CAM Fee	Appt Fee/Misc	Total Amount Due
$ 290.00	$ 1000	$	$	$ 250	$	$	$ [redacted]

NOTE: *In addition to all other costs, G.S. 7A-304(a)(10) requires a fee of $100.00 for a conviction of any of the four offenses sentenced on this form.*

*See attached "Restitution Worksheet, Notice And Order (Initial Sentencing)" AOC-CR-611, which is incorporated by reference.

☐ The Court finds just cause to waive costs, as ordered on the attached ☐ AOC-CR-618, ☐ Other: _____

REGULAR CONDITIONS OF PROBATION - G.S. 15A-1343(b)

NOTE: *Any probationary judgment may be extended pursuant to G.S. 15A-1342.*

The defendant shall: (1) Commit no criminal offense in any jurisdiction. (2) Possess no firearm, explosive device or other deadly weapon listed in G.S. 14-269. (3) Remain gainfully and suitably employed or faithfully pursue a course of study or vocational training, that will equip the defendant for suitable employment, and abide by all rules of the institution. (4) Satisfy child support and family obligations, as required by the Court. (5) Submit to the taking of digitized photographs, including photographs of the defendant's face, scars, marks, and tattoos, to be included in the defendant's records.

If the defendant is on supervised probation, the defendant shall also: (6) Not abscond, by willfully avoiding supervision or by willfully making the defendant's whereabouts unknown to the supervising probation officer. (7) Remain within the jurisdiction of the Court unless granted written permission to leave by the Court or the probation officer. (8) Report as directed by the Court or the probation officer to the officer at reasonable times and places and in a reasonable manner, permit the officer to visit at reasonable times, answer all reasonable inquiries by the officer and obtain prior approval from the officer for, and notify the officer of, any change in address or employment. (9) Notify the probation officer if the defendant fails to obtain or retain satisfactory employment. (10) Submit at reasonable times to warrantless searches by a probation officer of the defendant's person and of the defendant's vehicle and premises while the defendant is present, for purposes directly related to the probation supervision, but the defendant may not be required to submit to any other search that would otherwise be unlawful.

Original - File Copy - DMV

Material opposite unmarked squares is to be disregarded as surplusage.

(11) Submit to warrantless searches by a law enforcement officer of the defendant's person and of the defendant's vehicle, upon a reasonable suspicion that the defendant is engaged in criminal activity or is in possession of a firearm, explosive device, or other deadly weapon listed in G.S. 14-269 without written permission of the court. (12) Not use, possess, or control any illegal drug or controlled substance unless it has been prescribed for the defendant by a licensed physician and is in the original container with the prescription number affixed on it; not knowingly associate with any known or previously convicted users, possessors, or sellers of any such illegal drugs or controlled substances; and not knowingly be present at or frequent any place where such illegal drugs or controlled substances are sold, kept, or used. (13) Supply a breath, urine, or blood specimen for analysis of the possible presence of prohibited drugs or alcohol when instructed by the defendant's probation officer for purposes directly related to the probation supervision. If the results of the analysis are positive, the probationer may be required to reimburse the Division of Adult Correction and Juvenile Justice for the actual costs of drugs or alcohol screening and testing.

If the defendant is to serve an active sentence as a condition of special probation, the defendant shall also: (14) Obey the rules and regulations of the Division of Adult Correction and Juvenile Justice governing the conduct of inmates while imprisoned. (15) If placed on supervised probation above, report to a probation officer in the State of North Carolina within seventy-two (72) hours of the defendant's discharge from the active term of imprisonment.

SPECIAL CONDITIONS OF PROBATION - G.S. 15A-1343(b1); 20-179

16. Obtain a substance abuse assessment and all recommended education or treatment.

☒ 17. Surrender the defendant's drivers license to the Clerk of Superior Court for transmittal/notification to the Division of Motor Vehicles; and not operate a motor vehicle until the defendant's driving privilege is restored by that Division, except as may be permitted in a limited privilege.

☒ 18. Complete 72 hours of community service during the first ~~180~~ 150 days of the period of probation, as directed by the judicial service coordinator. The fee prescribed by G.S. 143B-708 is ☐ not due because it is assessed in a case adjudicated during the same term of court. ☐ to be paid ☑ pursuant to the schedule set out under Monetary Conditions above ☐ within _____ days of this Judgment and before beginning service.

☐ 19. Abstain from alcohol consumption for _____ ☐ days, ☐ months, as verified by a continuous alcohol monitoring (CAM) system.

a. The fees for the system shall be paid directly to the monitoring provider by ☐ the defendant. ☐ _____, the local government entity responsible for the defendant's incarceration in the local confinement facility, upon the Court's finding, for good cause shown, that the defendant should not be required to pay the fees and the local government's agreement to pay them.

~~☐ b. (Levels 1 and 2, only) The defendant shall be given credit against this period of abstinence and monitoring for (maximum of 60) _____ days spent on CAM prior to trial.~~

☐ 20. Other:

[Check any that apply - G.S. 20-179(f)]

☐ The probation officer may transfer the defendant to unsupervised probation upon completion of ☐ the community service required by Special Condition No. 18 above. ☐ payment of the "Total Amount Due" on the reverse.

SPECIAL ALCOHOL CONCENTRATION FINDING

☐ The defendant's alcohol concentration was 0.15 or greater. ☐ Other:

ORDER OF COMMITMENT/APPEAL ENTRIES

☐ 1. It is ORDERED that the Clerk deliver two certified copies of this Commitment on Special Probation to the sheriff or other qualified officer and that the officer cause the defendant to be delivered with these copies to the custody of the agency named on the reverse to serve the sentence imposed or until the defendant shall have complied with the conditions of release pending appeal.

☐ 2. The defendant gives notice of appeal from the judgment of the District Court to the Superior Court. The current pretrial release order is modified as follows: _____

NOTE: *Withdrawal of appeal or remand to District Court requires that a new sentencing hearing be scheduled in District Court, unless certain conditions are met. G.S. 20-38.7(c).*

☐ 3. The defendant gives notice of appeal from the judgment of the Superior Court to the appellate division. Appeal entries and any conditions of post-conviction release are set forth on form AOC-CR-350.

SIGNATURE OF JUDGE

Date	Name Of Presiding Judge (type or print)	Signature Of Presiding Judge
7/30/20	[illegible]	[signature]

CERTIFICATION

I certify that this Judgment and the attachment(s) marked below are true and complete copies of the originals.

☐ 1. Determination Of Sentencing Factors (AOC-CR-311, Rev. 12/15) ☐ 3. Other: _____

☐ 2. Restitution Worksheet, Notice And Order (Initial Sentencing) (AOC-CR-611)

Date	Date Certified Copies Delivered To Sheriff	Signature Of Clerk	☐ Deputy CSC ☐ Asst. CSC ☐ Clerk Of Superior Court	SEAL

NOTE TO CLERK: *If the defendant's conviction is based on a violation of an offense involving impaired driving while the defendant's drivers license is revoked as a result of a prior impaired driving license revocation as defined in G.S. 20-28.2, report DWI Defendant Registration Stop to DMV using mess item #9 in STARS. Also report the defendant's conviction to DMV in the usual manner. If there is a non-defendant vehicle owner, report registration stop to DMV using mess item #10 in STARS (unless the owner has been found to be an innocent owner).*

Material opposite unmarked squares is to be disregarded as surplusage.

© 2018 Administrative Office of the Courts

NORTH CAROLINA UNIFORM CITATION - COURT COPY

Citation No. 059711G

STATE OF NORTH CAROLINA New Hanover County District Court File No. 2020CR 707215

TO THE DEFENDANT NAMED BELOW: You have been charged with the misdemeanor(s) or infraction(s) specified below. Read this citation carefully.

YOUR COURT DATE AND LOCATION

Court Day	Date	Time	Court Location	Courtroom	Interpreter	Agency Case Number
Wed	09/16/2020	09:00AM	WILMINGTON	0200		

THE STATE OF NORTH CAROLINA VS.

State	Source	Name Of Defendant	Race	Gender
NC	DL	WHITE, FRANK NEAL	White	Male

CDL	Class			Age
No	C	[redacted]		41

[redacted] City: RALEIGH State: NC Zip: [redacted]

CHARGING OFFICER INFORMATION

Date	Signature Of Officer	No.	Law Enforcement Agency	Troop/Squad	District/Zone
07/06/2020	Trp. D R KEY	1591	STATE HIGHWAY PATROL	B	6

WHAT YOU ARE CHARGED WITH

The officer named below has probable cause to believe that on or about Sunday the 05 day of July 2020 at 10:46PM in the county named above you did unlawfully and willfully

OPERATE A MOTOR VEHICLE ON A STREET OR HIGHWAY WHILE SUBJECT TO AN IMPAIRING SUBSTANCE (G.S. 20-138.1)

~~and on or about Sunday the 05 day of July 2020 at 10:46PM in the county named above you did unlawfully and willfully~~

MISDEMEANOR CHILD ABUSE (G.S. 14-318.2)

YOUR VEHICLE

Vehicle License No.	State	Trailer Type	CMV	Vehicle Type	Vehicle Make	Year	Haz. Mat.
25876341	NC		No	Passenger (2 or 4-Door Sedan)	TESLA	2020	No

OTHER INFORMATION

Area	Weather	Visibility	Traffic	Accident	Speed	On Highway No./Street
Business	Clear	Clear	Light	I-03	A 45	S R1402

☒ Injury or Serious Injury ☐ Passengers Under 16	SHP Code	In Vicinity/City Of	At/Near Intersection
	06	WILMINGTON	VOWELL AVENUE

WITNESSES

Witness #1 | Witness #2 | Witness #3

OFFICER COMMENTS

SEE DWIR

COURT USE ONLY

District Attorney | Attorney For Defendant At Time Of Trial Or Plea ☐ Appointed ☐ Retained ☐ Waived

PRIOR CONVICTIONS: No/Level: 0 ☐ I(0) ☐ II (1-4) ☐ III (5+)

PLEA: ☑ guilty/resp. ☐ no contest ☐ not guilty/resp.

VERDICT/PENDING: ☑ guilty/resp. DWI David Rhue ☐ guilty/resp. ☐ not guilty/resp. ☐ W/D

M.C.L. ☐ A1 ☐ 1 ☐ 2 ☐ 3

M.C.L. ☑ A1 ☐ 1 ☐ 2 ☐ 3

JUDGMENT: The defendant appeared in open court and freely, voluntarily and understandingly entered the above plea; on the above verdict/finding, it is ORDERED that the defendant: ☐ pay costs and a fine/penalty of $_____. ☐ be imprisoned for a term of _____ days in custody of the sheriff. Pretrial credit _____ days served. ☐ The Court finds that a ☐ longer ☐ shorter period of probation than specified in G.S. 15A-1343.2(d) is necessary. ☐ Execution of sentence is suspended and the defendant is placed on unsupervised probation for _____ months, subject to the regular conditions of probation and the following: ☐ (1) pay costs and a fine/penalty of $_____. ☐ (2) not operate a motor vehicle until properly licensed by DMV. ☐ (3) complete _____ hours of community service within _____ days and pay the fee. ☐ (4) Other: Separate for DWI see Joint Form / for child abuse see 20 CR 704136

It is ORDERED that this: ☐ Judgment is continued upon payment of costs. ☐ case be consolidated for judgment with _____ ☐ sentence is to run at the expiration of the sentence in _____ ☐ The Court finds just cause to waive costs as ordered on attached ☐ AOC-CR-618, ☐ Other: _____

COMMITMENT: It is ORDERED that the Clerk deliver two (2) certified copies of this Judgment and Commitment to the sheriff and that the sheriff cause the defendant to be retained in custody to serve the sentence imposed or until the defendant shall have complied with the conditions of release pending appeal.

☐ The defendant in open court gives notice of appeal to the Superior Court.

☐ The current pretrial release order is modified as follows: _____

Date	Signature of Judge/Clerk/Magistrate	I certify that this Judgment is a true copy.	Date	Signature Of Deputy/Assistant CSC
7/30/20	[signature]			

AOC-CR-500 (CITATION), Rev. 12/12 (Structured Sentencing). © 2012 Administrative Office of the Courts

NORTH CAROLINA UNIFORM CITATION - COURT COPY

STATE OF NORTH CAROLINA New Hanover County District Court File No. 2020IF 704126 | Citation No. 059710G

TO THE DEFENDANT NAMED BELOW: You have been charged with the misdemeanor(s) or infraction(s) specified below. Read this citation carefully.

YOUR COURT DATE AND LOCATION

Court Day	Date	Time	Court Location	Courtroom	Interpreter	Agency Case Number
Wed	09/16/2020	09:00AM	WILMINGTON	0200		[redacted]

THE STATE OF NORTH CAROLINA VS.

State	Source	Name Of Defendant	Race
NC	DL	WHITE, FRANK NEAL	White

COL	Class	Gender
No	C	Male

[redacted]

City	State	Zip	Age
RALEIGH	NC	[redacted]	41

CHARGING OFFICER INFORMATION

Date	Signature Of Officer	No.	Law Enforcement Agency	Troop/Squad	District/Zone
07/06/2020	Trp. D R KEY	1591	STATE HIGHWAY PATROL	B	61

WHAT YOU ARE CHARGED WITH

The officer named below has probable cause to believe that on or about Sunday, the 05 day of July, 2020 at 10:46PM in the county named above you did unlawfully and willfully

OPERATE A MOTOR VEHICLE ON A STREET OR HIGHWAY BY FAILING TO MAINTAIN LANE CONTROL WITHIN A SINGLE LANE WHILE DRIVING ON A STREET WITH CLEARLY MARKED LANES FOR TRAFFIC (G.S. 20-146(D)(1))

and on or about Sunday, the 05 day of July, 2020 at 10:46PM in the county named above you did unlawfully and willfully

OPERATE A MOTOR VEHICLE ON A STREET OR HIGHWAY BY TRANSPORTING A PASSENGER OF LESS THAN 16 YEARS OF AGE WITHOUT HAVING THE PASSENGER IN A WEIGHT APPROPRIATE CHILD PASSENGER RESTRAINT SYSTEM. (G.S. 20-137.1)

YOUR VEHICLE

Vehicle License No.	State	Trailer Type	CMV	Vehicle Type	Vehicle Make	Year	Haz. Mat.
25876341	NC		No	Passenger (2 or 4-Door Sedan)	TESLA	2020	No

OTHER INFORMATION

Area	Weather	Visibility	Traffic	Accident	Speed	On Highway No./Street
Business	Clear	Clear	Light	I-03	A 45	S R1402

☒ Injury or Serious Injury ☐ Passengers Under 16	SHP Code	In Vicinity/City Of	At/Near Intersection
	06	WILMINGTON	VOWELL AVENUE

WITNESSES

Witness #1 | Witness #2 | Witness #3

OFFICER COMMENTS

SEE DWIR AND DMV 349

COURT USE ONLY

District Attorney | Attorney For Defendant At Time Of Trial Or Plea: ☐ Appointed ☐ Retained ☒ Waived

PRIOR CONVICTIONS: No./Level: 0 ☐ I (0) ☐ II (1-4) ☐ III (5+)

PLEA: ☒ guilty/resp. ☐ no contest ☐ not guilty/resp.

VERDICT/PENDING: ☒ guilty/resp. 20-146 (D)(1) ☒ guilty/resp. 20-137.1 ☐ not guilty/resp.

M.C.L. ☐ A1 ☐ 1 ☐ 2 ☐ 3

M.C.L. ☐ A1 ☐ 1 ☐ 2 ☐ 3

☐ WD

JUDGMENT: The defendant appeared in open court and freely, voluntarily and understandingly entered the above plea; on the above verdict/finding, it is ORDERED that the defendant:

☐ pay costs and a fine/penalty of $ _____. ☒ be imprisoned for a term of 45 days in custody of the sheriff. Pretrial credit _____ days served. ☐ The Court finds that a ☐ longer ☐ shorter period of probation than specified in G.S. 15A-1343.2(d) is necessary. ☐ Execution of sentence is suspended, the defendant is placed on unsupervised probation for 18 months, subject to the regular conditions of probation and the following: ☐ (1) pay costs and a fine/penalty of $ 50. ☐ (2) not operate a motor vehicle until properly licensed by DMV. ☐ (3) complete _____ hours of community service within _____ days and pay the fee. ☐ (4) Other: _____

It is ORDERED that this: ☐ Judgment is continued upon payment of costs. ☒ case be consolidated for judgment with (M) Child Abuse TH 20CR 707215 ☒ sentence is to run at the expiration of the sentence in 20 CR 707215. ☐ The Court finds just cause to waive costs as ordered on attached ☐ AOC-CR-618. ☐ Other: _____

☐ COMMITMENT: It is ORDERED that the Clerk deliver two (2) certified copies of this Judgment and Commitment to the sheriff and that the sheriff cause the defendant to be detained in custody to serve the sentence imposed or until the defendant shall have complied with the conditions of release pending appeal.

☐ The defendant in open court gives notice of appeal to the Superior Court.

☐ The current pretrial release order is modified as follows: _____

Date	Signature Of Clerk/Assistant/CSC	I certify that this Judgment is a true copy.	Date	Signature Of Deputy/Assistant CSC
7/30/20	[signature]			

AOC-CR-500 (eCITATION), Rev. 12/12 (Structured Sentencing). © 2012 Administrative Office of the Courts

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Paragon Implant Company, LLC

Physical Address: 8840 West Russell Road, Suite 200

City: Las Vegas State: NV Zip: 89148

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: (702) 268-7217 Website: www.paragon-implant.com

Name of Designated Representative (DR): Gerald Niznick

Licensing Company Email: jkonheim@paragon-implant.com DR Email: niznick@paragon-implant.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Dental Labs		■ Others: Packaging/Labeling

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No business conducted. Just getting started. The following will be our primary suppliers.

Address: _____ City: _____ State: _____ Zip: _____

Name: Paragon Implant Mfg., LLC

Address: 27030 Malibu Hills Road City: Calabasas State: CA Zip: 91301

Name: Geryon Holdings (DESS Dental Products)

Address: 1025 Greenwood Boulevard, Suite 101 City: Lake Mary State: FL Zip: 32746

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Paragon Implant Company, LLC

Mailing Address: 8840 West Russell Road, Suite 200

City: Las Vegas State: NV Zip: 89148

Telephone: (702) 268-7217 Email: jkonheim@paragon-implant.com

Contact Person Name: Jon Konheim

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Paragon Implant Company, LLC

Facility Name

Gerald Niznick

Print Name of Authorized Person Submitting Application

Dr. Gerald Niznick

Original signature of Authorized Person (copies or stamps not accepted)

11/21/24

Date

Board Use Only	Date Received: 12/3/24	Amount: $1000 cc

PARAGON
IMPLANT COMPANY

Wholesaler Application

Section 8

1. FDA Registration – see attached
2. Bond for $25,000 payable to the State of Nevada

Section 9

1. List of all Officers and Directors
    a. Gerald Niznick, Chief Executive Officer and President
    b. Jon Konheim, Chief Operating Officer and Chief Financial Officer
    c. Josephine Jurcoane, Director of Marketing and General Manager of Las Vegas Site
2. List of all shareholders and percentage ownership
    a. Niznick Family Dynasty Trust – 90%
    b. Mikana Manufacturing Company – 10%
3. Certificate of Good Standing – see attached
4. Designated Representative Form – see attached
5. Personal History Record Application for each owner – see attached
6. Copy of DEA certificate – not applicable
7. List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant
    a. Employees
        i. Jon Konheim
        ii. Josephine Jurcoane
        iii. Andrea Mason
        iv. Michael Amitrano
        v. Mhansi Pandhi
8. Copy of out-of-state license – not applicable
9. MDEG Administrator Form – see attached
10. Liability Insurance covering at least $1,000,000 – see attached

PARAGON
IMPLANT COMPANY

Section 8

1. FDA Registration

From: CDRH Registration and Listing
To: Renee Bennett
Subject: Successful 2025 Medical Device Establishment Registration
Date: Sunday, October 27, 2024 6:55:01 AM
Attachments: SignatureBlockLogo.png

Dear Renee Bennett:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2025:

Registration Number:
Owner Operator Number: 10091708
PARAGON IMPLANT COMPANY, LLC
8840 W Russell Rd Ste 200
Las Vegas, NV 89148
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2025. Registration for 2026 will be conducted between October 1 and December 31, 2025.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Imports & Registration and Listing Team
Division 2 Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1
Email: reglist@cdrh.fda.gov

Registration Information

Facility

Registration Number

FEI Number

Registration Status
Active, Waiting for Registration Number Assignment

Registration Status Reason
New registration created

Initial Importer
N

Facility Name
PARAGON IMPLANT COMPANY, LLC

Legal Name

Facility Address
8840 W RUSSELL RD STE 200
LAS VEGAS, NEVADA, 89148, UNITED STATES

DUNS Number
119983353

Foreign Trade Zone
N

Facility URL

Other Business Trade Name(s)

Establishment located on a campus
N

Owner/Operator

Owner/Operator Number
10091708

Contact Name
RENEE BENNETT

Business Name
PARAGON IMPLANT COMPANY, LLC

Address
8840 WEST RUSSELL ROAD
LAS VEGAS, NEVADA, 89148, UNITED STATES

Phone Number
818 - 4754675

Fax Number

E-mail rbennett@paragon-implant.com

DUNS Number
119983353

Official Correspondent

Contact Name
RENEE BENNETT

Business Name
PARAGON IMPLANT COMPANY, LLC

Address
8840 WEST RUSSELL ROAD
LAS VEGAS, NEVADA, 89148, UNITED STATES

Phone Number
818 - 4754675

Fax Number

E-mail rbennett@paragon-implant.com

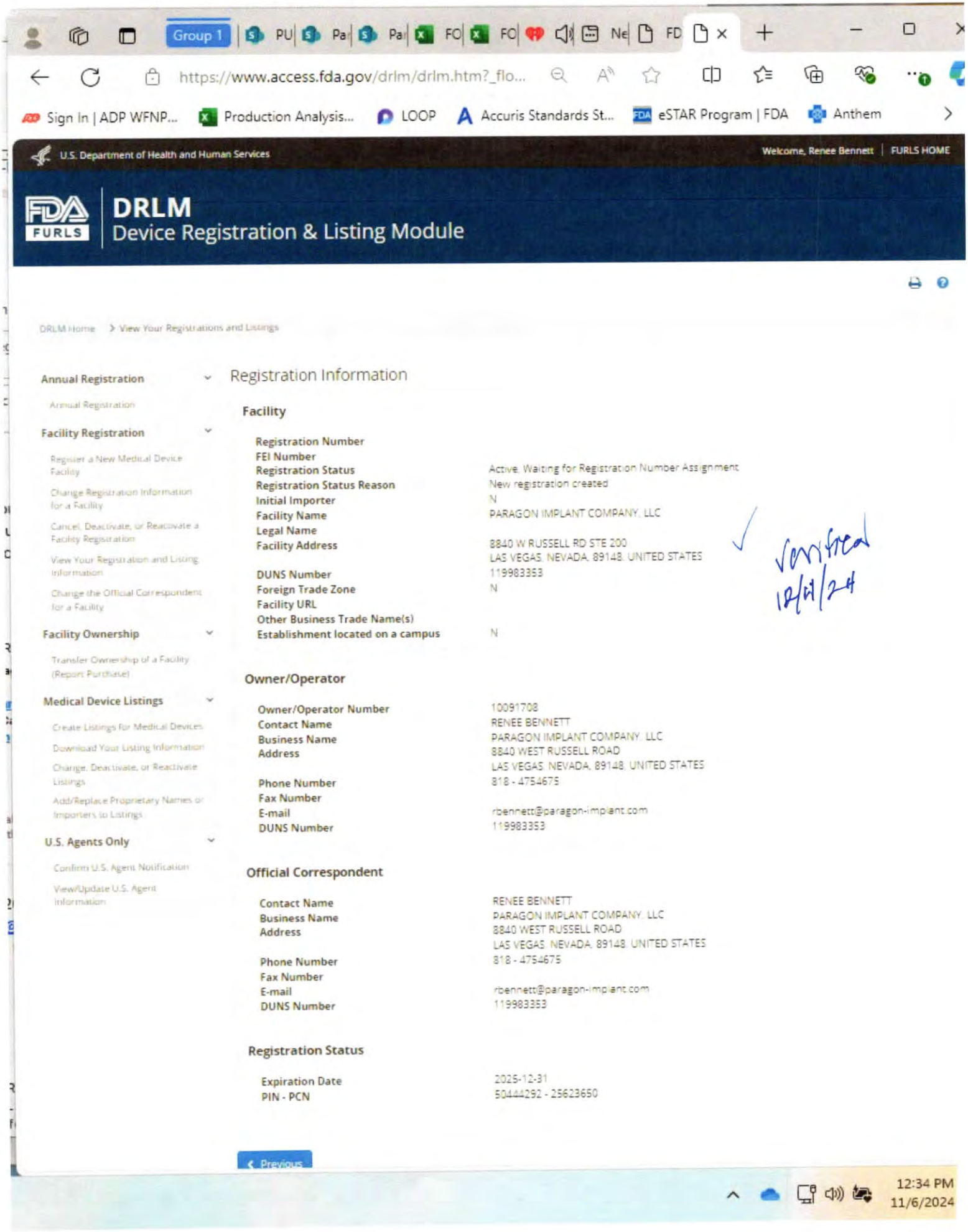
DUNS Number
119983353

Registration Status

Expiration Date
2025-12-31

PIN - PCN
50444292 - 25623650

< Previous (drlm.htm?_flowExecutionKey=_c5D8E2E75-F4FE-4A4F-84D2-BBAF6E19CC81_k55B4284E-917E-0624-186A-3AD4DDA9E390&_eventId=back)


https://www.access.fda.gov/drlm/drlm.htm?_flo...
Sign In | ADP WFNP...
Production Analysis...
LOOP
Accuris Standards St...
eSTAR Program | FDA
Anthem
U.S. Department of Health and Human Services
Welcome, Renee Bennett | FURLS HOME
FDA FURLS
DRLM
Device Registration & Listing Module
DRLM Home > View Your Registrations and Listings
Annual Registration
Annual Registration
Facility Registration
Register a New Medical Device Facility
Change Registration Information for a Facility
Cancel, Deactivate, or Reactivate a Facility Registration
View Your Registration and Listing Information
Change the Official Correspondent for a Facility
Facility Ownership
Transfer Ownership of a Facility (Report Purchase)
Medical Device Listings
Create Listings for Medical Devices
Download Your Listing Information
Change, Deactivate, or Reactivate Listings
Add/Replace Proprietary Names or Importers to Listings
U.S. Agents Only
Confirm U.S. Agent Notification
View/Update U.S. Agent Information
Registration Information
Facility
Registration Number
FEI Number
Registration Status
Active. Waiting for Registration Number Assignment
Registration Status Reason
New registration created
Initial Importer
N
Facility Name
PARAGON IMPLANT COMPANY, LLC
Legal Name
Facility Address
8840 W RUSSELL RD STE 200
LAS VEGAS, NEVADA, 89148, UNITED STATES
DUNS Number
119983353
Foreign Trade Zone
N
Facility URL
Other Business Trade Name(s)
Establishment located on a campus
N
Owner/Operator
Owner/Operator Number
10091708
Contact Name
RENEE BENNETT
Business Name
PARAGON IMPLANT COMPANY, LLC
Address
8840 WEST RUSSELL ROAD
LAS VEGAS, NEVADA, 89148, UNITED STATES
Phone Number
818 - 4754675
Fax Number
E-mail
rbennett@paragon-implant.com
DUNS Number
119983353
Official Correspondent
Contact Name
RENEE BENNETT
Business Name
PARAGON IMPLANT COMPANY, LLC
Address
8840 WEST RUSSELL ROAD
LAS VEGAS, NEVADA, 89148, UNITED STATES
Phone Number
818 - 4754675
Fax Number
E-mail
rbennett@paragon-implant.com
DUNS Number
119983353
Registration Status
Expiration Date
2025-12-31
PIN - PCN
50444292 - 25623650
Previous
Verified 12/11/24
12:34 PM
11/6/2024

PARAGON
IMPLANT COMPANY

Section 9

3. Certification of Good Standing

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Paragon Implant Company, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/25/2022, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/01/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202411015158142
You may verify this certificate online at https://www.nvsilverflume.gov/home

STATE OF NEVADA SALES TAX PERMIT
DEPARTMENT OF TAXATION

Taxpayer ID: 1044722274-001
Correspondence ID: 2400016691970
Date: 5/23/2024

PARAGON IMPLANT COMPANY LLC
8840 W RUSSELL RD STE 200
LAS VEGAS, NV 89148

THIS PERMIT:
IS NOT TRANSFERABLE TO ANY OTHER PERSON.
IS VOID IF ALTERED.
IS NOT ISSUED IN LIEU OF ANY LOCALLY REQUIRED BUSINESS LICENSE, PERMIT OR REGISTRATION.

Is authorized to collect Nevada sales tax at the following location if different from above.

Permit Location:
PARAGON IMPLANT COMPANY LLC
8840 W RUSSELL RD
LAS VEGAS, NV 89148

MUST BE DISPLAYED IN PUBLIC VIEW AT PERMIT LOCATION

(Detach Here)

Attached is your Nevada Sales Tax Permit.

A single number, the TID (Taxpayer Identification Number), identifies a taxpayer for MOST tax types. Please use your TID and LOC (Location Number) on resale certificates, in correspondence or telephone calls to the Department.

Based on your estimated monthly taxable receipts as stated on the Nevada Business Registration Supplemental application, your filing frequency will be Quarterly.

As stated on the application, your business start date is 12/1/2023 making your first remittance due on or before 1/31/2024

The Department of Taxation has forms, publications and information available via internet at **https://tax.nv.gov.**

The Department of Taxation is providing businesses with the ability to view and manage their accounts via the internet through its interactive website, NevadaTax, located at ***https://nevadatax.nv.gov/***. Businesses can file tax returns, make payments, and view financials associated with their Sales and Use Tax account, Modified Business Tax account, and Business License account.

A business must first register and receive a username and password before NevadaTax will allow access to view and manage accounts. If you are already registered to use NevadaTax, this tax type will be added to your existing account.

Your business should use the following Pre-approved NevadaTax Activation Code when registering to use NevadaTax: Pre-approved NevadaTax Activation Code: **61B9F727-C542-4756-AD84-EF8BAC41AC8F**

The Nevada Sales Tax Permit has been issued pursuant to an application duly filed and payment of prescribed fees. This Sales Tax Permit is subject to the provisions of Nevada Revised Statutes 372, 374, and 377. This Sales Tax Permit shall be considered valid unless canceled, suspended or revoked for good cause in accordance with Title 32.

Electronically Filed

DISTRICT OFFICE LOCATIONS

CARSON CITY MAIN OFFICE	RENO OFFICE	LAS VEGAS OFFICE
1550 College Parkway, Suite 115 Carson City, Nevada, 89706 Phone: (775) 684-2000	4600 Kietzke Lane Building L, Suite 235 Reno, Nevada, 89502 Phone: (775) 687-9999	700 E. Warm Springs Road, Suite 200 Las Vegas, Nevada, 89119 Phone: (775) 486-2300

In the event of an address change, please notify the Department of Taxation immediately in order to direct any correspondence to your new address.

PARAGON
IMPLANT COMPANY

10. Liability Insurance covering at least $1,000,000

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 05/17/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Joseph Avila	
Dochterman Insurance Services, Inc. 4 Park Plaza Suite 1750 Irvine CA 92614	PHONE (A/C, No, Ext): (626) 217-9000	FAX (A/C, No): (626) 217-9999
	E-MAIL ADDRESS: joseph@dochterman.com	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Paragon Implant MFG, LLC 27030 Malibu Hills Rd Agoura Hills CA 91301	INSURER A: Arch Insurance Company	11150
	INSURER B: Preferred Employers Insurance Company	10900
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** CL2451712350 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			PMPKG0028002	05/17/2024	05/17/2025	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
							Employee Benefits	$ 1,000,000
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			PMPKG0028002	05/17/2024	05/17/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
							Underinsured motorist	$ 1,000,000
A	[ ] UMBRELLA LIAB [ ] OCCUR [X] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			PMFXS0016702	05/17/2024	05/17/2025	EACH OCCURRENCE	$ 5,000,000
							AGGREGATE	$ 5,000,000
								$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [Y] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			PXN 173696-2	05/17/2024	05/17/2025	[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

*10 days notice of cancellation for non-payment of premium.

CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Joseph Avila

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The ACORD name and logo are registered marks of ACORD

Additional Named Insureds

Other Named Insureds	
Discovery Gateway Park, LLC	
Gerald A. Niznick Family Trust	
Niznick 2004 Grandchildren's Trust	
Niznick Dynasty Trust dated December 24th, 2020	
Niznick Enterprises, Inc.	
Paragon Implant Company LLC	Additional Named Insured

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PARAGON
IMPLANT COMPANY

2. Bond for $25,000 payable to the State of Nevada

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 5336568

Application/License No. _____

Paragon Implant Company, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8840 W. Russell Road, Suite 200 Las Vegas, NE 89148 (Address of Applicant/Principal), as PRINCIPAL, and SureTec Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2103 CityWest Boulevard, Suite 1300 Houston, TX 77042 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 25, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Bond No. 5336568

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of November, 2024.

APPLICANT/PRINCIPAL
Paragon Implant Company, LLC

Authorized Representative

SURETY COMPANY
SureTec Insurance Company

Janelle L Tuominen
Surety Company's Representative

Janelle L. Tuominen, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

POA #: 5336568

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Janelle L. Tuominen

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

Principal: Paragon Implant Company, LLC
Obligee: Nevada State Board of Pharmacy
Amount: $ 25,000.00

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and of behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly sworn, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 126571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 25th day of November, 2024, A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power you may call (713) 812-0800 any business day between 8:30 am and 5:00 pm CST.

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA

County of Riverside }

On November 25, 2024 (Date) before me, Susan C. Monteon (Insert Name of Notary exactly as it appears on the official seal), Notary Public,

personally appeared Janelle L. Tuominen (Name(s) of Signer(s)),

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

Witness my hand and official seal.

Signature Susan C Monteon
Signature of Notary Public Susan C. Monteon

SUSAN C. MONTEON
COMM. #2365920
Notary Public - California
Riverside County
My Comm. Expires July 16, 2025

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of the form to another document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____
☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

Signer's Name: _____
☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

PARAGON
IMPLANT COMPANY

9. MDEG Administrator Form

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Paragon Implant Company, LLC — MDEG License # (if applicable): _____
Physical Address: 8840 West Russell Road, Suite 200
City: Las Vegas — State: NV — Zip: 89148
Mailing Address (if different from physical address): _____
City: _____ — State: _____ — Zip: _____
Telephone: (702) 268-7217 — Website: www.paragon-implant.com
Licensing Company Email: jkonheim@paragon-implant.com

Section 2: Personal Information

First: Gerald — Middle: Alvin — Last: Niznick
Alias(es, nicknames, name changes, etc.): _____
Date of Birth: [redacted] — SSN or ITI: [redacted] — Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted]
City: [redacted] — State: NV — Zip: 89148
Telephone: (702) 494-8474 — Email: niznick@paragon-implant.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California School of Dentistry		09/86 - 05/87	
Address	**City**	**State**	**Zip**
925 West 34th Street	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Certificate in Prosthetics			

School Name		From - To (MM/YY – MM/YY)	
Indiana University School of Dentistry		07/66 - 09/67	
Address	**City**	**State**	**Zip**
5685 Lafayette Rd.	Indianapolis	IN	46254
Diploma/Degree obtained, if any			
MSD			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba College of Dentistry (Dr. Gerald Niznick College of Dentistry)		09/62 - 05/66	
Address	**City**	**State**	**Zip**
790 Bannatyne Ave	Winnepeg	MB	R3E 0W3
Diploma/Degree obtained, if any			
Doctor Dental Medicine			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba		09/60 - 05/62	
Address	**City**	**State**	**Zip**
66 Chancellors Cir	Winnepeg	MB	R3T 2N2
Diploma/Degree obtained, if any			
2 years Pre-Dental			

School Name		From - To (MM/YY – MM/YY	
West Kildonan Collegiate		09/58 - 05/60	
Address	**City**	**State**	**Zip**
101 Ridgecrest Ave	Winnepeg	MB	R2V 4T6
Diploma/Degree obtained, if any			
High School Degree			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/24-Present	[redacted]	[redacted]	NV	89169
09/10-07/24			NV	89158

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Implant Direct International, LLC		01/06-02/14	
Business Address	**City**	**State**	**Zip**
8840 West Russell Road, Suite 200	Las Vegas	NV	89148
Phone	**Title**	**Number of Employed Hours**	
(702) 268-7217	Chief Executive Officer/President	226,720	
Description of Duties			
Oversee entire operation of the business.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Dr Herald Klimisch

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

I, Gerald Niznick, **certify that as the MDEG Administrator for**

Paragon Implant Company, LLC,

that I (initial that you have read and meet the following requirements):

1. GN Have a high school diploma or its equivalent;
2. GN Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. GN Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. GN Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gerald Niznick
Print Name (First, Last)

Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Board Use Only	Date Received:

PARAGON
IMPLANT COMPANY

4. Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Paragon Implant Company, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 8840 West Russell Road, Suite 200

City: Las Vegas State: NV Zip: 89148

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (702) 268-7217 Website: www.paragon-implant.com

Licensing Company Email: jkonheim@paragon-implant.com

Section 2: Personal Information

First: Gerald Middle: Alvin Last: Niznick

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: NV Zip: 89148

Telephone: (702) 494-8474 Email: niznick@paragon-implant.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Indiana University School of Dentistry		07/66 - 09/67	
Address	City	State	Zip
5685 Lafayette Rd.	Indianapolis	IN	46254
Diploma/Degree obtained, if any			
MSD			

School Name		From - To (MM/YY – MM/YY)	
University of Southern California School of Dentistry			
Address	City	State	Zip
925 West 34th Street	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Certificate in Prosthetics			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba College of Dentistry (Dr. Gerald Niznick College of Dentistry)		09/62 - 05/66	
Address	City	State	Zip
790 Bannatyne Ave	Winnepeg	MB	R3E 0W3
Diploma/Degree obtained, if any			
Doctor Dental Medicine			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba		09/60 - 05/62	
Address	City	State	Zip
66 Chancellors Cir	Winnepeg	MB	R3T 2N2
Diploma/Degree obtained, if any			
2 years Pre-Dental			

School Name		From - To (MM/YY – MM/YY	
West Kildonan Collegiate		09/58 - 05/60	
Address	City	State	Zip
101 Ridgecrest Ave	Winnepeg	MB	R2V 4T6
Diploma/Degree obtained, if any			
High School Degree			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/24 - Present	[redacted]	[redacted]	NV	89169
09/10 - 07/24			NV	89158

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Implant Direct International, LLC		01/06 - 02/14	
Business Address	**City**	**State**	**Zip**
8840 West Russell Road, Suite 200	Las Vegas	NV	89148
Phone	**Title**	**Number of Employed Hours**	
702-268-7217	Chief Executive Officer / President	226,720	
Description of Duties			
Oversee entire operation of the business.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Gerald Niznick, **certify that as the designated representative for**

Paragon Implant Company, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gerald Niznick

Print Name (First, Last)

Dr Gerald Niznick

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gerald Niznick

Print Name (First, Last)

Dr Gerald Niznick

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Gerald Niznick, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Dr Gerald Niznick

Original Signature

11/21/24

Date

Subscribed and Sworn to before me this 21 day of NOV. 2024

Joseph Mina

Notary Public Signature

JOSEPH MINA
Notary Public - California
Los Angeles County
Commission # 2367367
My Comm. Expires Aug 19, 2025

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Jun-01	Feb-16	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-11-644240-C		Eighth Judicial District Court		
Reason/Charge				
Other Civil Matter				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Core-Vent Bio-Engineering Inc, (Plaintiffs) vs. Polo Nevada Inve			Lawsuit	
Name of Business/Industry/Entity				
Core Vent Bio-Engineering, Inc				

Provide explanation below:

Dispute over investment in Polo Towers, dispute resolved by defendant agreeing to pay plaintiff 1.5M.

Dr Gerald Nizmik

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

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This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Feb-02	Jan-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A447086		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Copper Sales Inc vs High Rise JV LLC, J A Jones Construction			Lawsuit/Third Party Defendant	
Name of Business/Industry/Entity				
Copper Sales Inc.				

Provide explanation below:

A dispute over a $7.8 million change order led to a lawsuit between the developer of the Park Towers At Hughes Center luxury condominiums in Las Vegas and its contractor, J.A. Jones Construction Co. Dr. Niznick, a resident of Park Tower at the time, is named a "Third-party defendant" due to the lien placed on the building.

Dr. Gerald Niznick

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

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This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
May-95	Sep-99	WA	Seattle	King County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:1995cv00709		Washington Western District Court		
Reason/Charge				
Patent/Trademark Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Genetic Implant Systems, Inc. v. Core-Vent Corp. and Gerald A.			Lawsuit	
Name of Business/Industry/Entity				
Core Vent Corp, et al				

Provide explanation below:

May-95 Sep-99 WA Seattle King County 2:1995cv00709 Washington Western District Court Patent/Trademark Dispute Genetic Implant Systems, Inc. v. Core-Vent Corp. and Gerald A. Niznick Lawsuit Core Vent Corp, et al This case dealt with patent-related disputes. The court evaluated jurisdiction issues concerning Core-Vent's distributor relationships and trademark use in Washington state

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Nov-01	Dec-02	CA	Los Angeles	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:2001cv10229		California Central District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Executive Air LLC v. Nizjet 450 LLC, et. Al			Lawsuit	
Name of Business/Industry/Entity				
Executive Air				

Provide explanation below:

The case is related to a breach of contract over the purchase of an airplane from the Plaintiff. Defendant agreed to purchase the plane in "as is" condition. However, after this agreement was made the manufacturer could not certify the aircraft could perform to the specfications outlined in aircraft description. Defendant was not made aware of this certification, which was discussed between Plaintiff and manufacturer, "Raytheon". Defendent rescinded its Contract with Plaintiff "for failure of consideration and for Plaintiffs. inabiity/failure to deliver the plane contracted for". Summary adjudication on the issue of liability granted to Plaintiff.

Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Oct-00	May-01	CA	Los Angeles	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:2000cv11413		California Central District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Executive Air LLC			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

Dispute over Aircraft Purchase Agreement/ Fraud. Defendant cancelled the sale of the aircraft after Plaintiff posted $219k in escrow. The result concluded with both Plaintiff claims, Defendents counter-claims dismissed.

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jun-03	Feb-04	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
03A468598		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Maurice Owens			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

"10/29/2010Order of Dismissal Without Prejudice (Judicial Officer: Bixler, James)Debtors: Sheldon Cloobeck (Defendant), Decatur Harmon LLC (Defendant), Stephen J Cloobeck (Defendant), Richard Cloobeck (Defendant)Creditors: Gerald A Niznick (Plaintiff), Reesa Niznick (Plaintiff)Judgment: 10/29/2010, Docketed: 11/09/2010"

Dr. Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jul-02	Feb-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A453516		Eighth Judicial District Court		
Reason/Charge				
Property Title Issue				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Michael Huggins			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

This case is related to the sale of a residential property located at 8616 Scarsdale Drive in Las Vegas. Plaintiff loaned Defendant the funds to purchase the property , which was to be paid back to Plaintiff in instllments w/ agreed interest. Defandant later defaulted resulting in the title company proceeding with fthe foreclosure on the property. Plaintiff Awarded: $385,254.00 Attorney Fees: $0.00 Costs: $389.00 Interest Amount: $0.00 Total: $385643.00

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jun-02	Jan-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A452627		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs. Americana LLC, Paula Jones			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

Disposition: Entry Date & Time: 01/27/2003 @ 14:01 Description: SUMMARY JUDGMENT Debtor: Americana LLC Creditor: Niznick, Gerald Amount Awarded: $14000.00 Attorney Fees: $1000.00 Costs: $0.00 Interest Amount: $0.00 Total: $15000.00

Dr Gerald Niznick
Original Signature (electronic copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
May-03	Jan-10	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
03A468009		Eighth Judicial District Court		
Reason/Charge				
Civil Filing				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick, Reesa Niznick vs Sheldon Cloobeck, Decatur H			Lawsuit	
Name of Business/Industry/Entity				
Gerald & Reesa Niznick				

Provide explanation below:

"10/29/2010Order of Dismissal Without Prejudice (Judicial Officer: Bixler, James)Debtors: Sheldon Cloobeck (Defendant), Decatur Harmon LLC (Defendant), Stephen J Cloobeck (Defendant), Richard Cloobeck (Defendant)Creditors: Gerald A Niznick (Plaintiff), Reesa Niznick (Plaintiff)Judgment: 10/29/2010, Docketed: 11/09/2010"

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Feb-08		NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
08A575522		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Implant Direct LLC vs Durango Warm Springs LLC			Lawsuit	
Name of Business/Industry/Entity				
Implant Direct LLC				

Provide explanation below:

Dispute over a lease, Implant Direct prevailed defendant settle with $50,000 donation to foundation.

Dr. Gerald Komiss
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Mar-14	Mar-17	NY	New York	New York
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
650908/14		SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK : IAS		
Reason/Charge				
Disagreement over sale of final shares of company and valuation.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Sybron Canada Holdings et al. v. Gerald A. Niznick et al.			Lawsuit	
Name of Business/Industry/Entity				
Implant Direct				

Provide explanation below:

The lawsuit was a disagreement between the parties over the key dates triggering the buyout of the Niznick remaining percentage of the partnership with Sybron Canada Holdings and the valuation of the remaining interest of Niznick. Counter suits included claims for damages and dispute over non-compete. Sybron Canada Holding's Inc. prevailed in their right to exercise their option to buy Dr. Niznick's remaining shares of Implant Direct and the court order that Sybron pay 75M plus 25M in interest. The result of Niznick vs. Sybron was non-compete set to expire 03/22/2022.

Dr. Howard Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
May-06	May-06	CA	San Diego	San Diego
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
3:2006cv01135		Disagreement over Asset Purchase Agreement		
Reason/Charge				
Disagreement over Asset Purchase Agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Zimmer Dental Inc v. Niznick, et al			Arbitration	
Name of Business/Industry/Entity				
Zimmer Dental				

Provide explanation below:

The case of Zimmer Dental Inc. v. Gerald Niznick involved disputes over intellectual property, specifically dental implant patents and the advertising claims of innovation made by Zimmer Dental. The central issue arose after Zimmer Dental acquired Paragon Implant Company from Dr. Niznick in 2001, including several patents he had developed.

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

PARAGON
IMPLANT COMPANY

5. Personal History Record Application for each owner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Paragon Implant Company, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 8840 West Russell Road, Suite 200

City: Las Vegas State: NV Zip: 89148

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (702) 268-7217 Website: www.paragon-implant.com

Licensing Company Email: jkonheim@paragon-implant.com

Section 2: Personal Information

First: Gerald Middle: Alvin Last: Niznick

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: NV Zip: 89148

Telephone: (702) 494-8474 Email: niznick@paragon-implant.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California School of Dentistry		07/66 - 09/67	
Address	**City**	**State**	**Zip**
925 West 34th Street	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Certificate in Prosthetics			

School Name		From - To (MM/YY – MM/YY)	
Indiana University School of Dentistry		07/66 - 09/67	
Address	**City**	**State**	**Zip**
5685 Lafayette Rd.	Indianapolis	IN	46254
Diploma/Degree obtained, if any			
MSD			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba College of Dentistry (Dr. Gerald Niznick College of Dentistry)		09/62 - 05/66	
Address	**City**	**State**	**Zip**
790 Bannatyne Ave	Winnepeg	MB	R3E 0W3
Diploma/Degree obtained, if any			
Doctor Dental Medicine			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba		09/60 - 05/62	
Address	**City**	**State**	**Zip**
66 Chancellors Cir	Winnepeg	MB	R3T 2N2
Diploma/Degree obtained, if any			
2 years Pre-Dental			

School Name		From - To (MM/YY – MM/YY	
West Kildonan Collegiate		09/58 - 05/60	
Address	**City**	**State**	**Zip**
101 Ridgecrest Ave	Winnepeg	MB	R2V 4T6
Diploma/Degree obtained, if any			
High School Degree			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/24 - Present	[redacted]	[redacted]	NV	89169
09/10 - 07/24			NV	89158

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Bristol DoubleTree, Home2 and Bristol Event Center			12/11 - Present
Business Address	**City**	**State**	**Zip**
42 Century Drive	Bristol	CT	06010
Phone	**Title**		
(702) 494-8474	Managing Member		
Description of Duties			
Owner			

Business Name			From - To (MM/YY – MM/YY)
Acromil, LLC			12/02 - Present
Business Address	**City**	**State**	**Zip**
18421 Railroad Street	City of Industry	CA	91748
Phone	**Title**		
(626) 964-2522	Managing Member		
Description of Duties			
Owner			

Business Name			From - To (MM/YY – MM/YY)
Niznick Enterprises Incorporated			12/01 - Present
Business Address	**City**	**State**	**Zip**
8840 Russell Rd STE 200	Las Vegas	NV	89148
Phone	**Title**		
702-726-8742	President		
Description of Duties			
Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Feb-02	Jan-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A447086		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Copper Sales Inc vs High Rise JV LLC, J A Jones Construction			Lawsuit/Third Party Defendant	
Name of Business/Industry/Entity				
Copper Sales Inc.				

Provide explanation below:

A dispute over a $7.8 million change order led to a lawsuit between the developer of the Park Towers At Hughes Center luxury condominiums in Las Vegas and its contractor, J.A. Jones Construction Co. Dr. Niznick, a resident of Park Tower at the time, is named a "Third-party defendant" due to the lien placed on the building.

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Jun-01	Feb-16	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-11-644240-C		Eighth Judicial District Court		
Reason/Charge				
Other Civil Matter				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Core-Vent Bio-Engineering Inc, (Plaintiffs) vs. Polo Nevada Inve			Lawsuit	
Name of Business/Industry/Entity				
Core Vent Bio-Engineering, Inc				

Provide explanation below:

Dispute over investment in Polo Towers, dispute resolved by defendant agreeing to pay plaintiff 1.5M.

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Nov-01	Dec-02	CA	Los Angeles	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:2001cv10229		California Central District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Executive Air LLC v. Nizjet 450 LLC, et. Al			Lawsuit	
Name of Business/Industry/Entity				
Executive Air				

Provide explanation below:

The case is related to a breach of contract over the purchase of an airplane from the Plaintiff. Defendant agreed to purchase the plane in "as is" condition. However, after this agreement was made the manufacturer could not certify the aircraft could perform to the specfications outlined in aircraft description. Defendant was not made aware of this certification, which was discussed between Plaintiff and manufacturer, "Raytheon". Defendent rescinded its Contract with Plaintiff "for failure of consideration and for Plaintiffs. inabiity/failure to deliver the plane contracted for". Summary adjudication on the issue of liability granted to Plaintiff.

Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
May-95	Sep-99	WA	Seattle	King County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:1995cv00709		Washington Western District Court		
Reason/Charge				
Patent/Trademark Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Genetic Implant Systems, Inc. v. Core-Vent Corp. and Gerald A.			Lawsuit	
Name of Business/Industry/Entity				
Core Vent Corp, et al				

Provide explanation below:

May-95 Sep-99 WA Seattle King County 2:1995cv00709 Washington Western District Court Patent/Trademark Dispute Genetic Implant Systems, Inc. v. Core-Vent Corp. and Gerald A. Niznick Lawsuit Core Vent Corp, et al This case dealt with patent-related disputes. The court evaluated jurisdiction issues concerning Core-Vent's distributor relationships and trademark use in Washington state

Dr. Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Oct-00	May-01	CA	Los Angeles	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:2000cv11413		California Central District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Executive Air LLC			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

Dispute over Aircraft Purchase Agreement/ Fraud. Defendant cancelled the sale of the aircraft after Plaintiff posted $219k in escrow. The result concluded with both Plaintiff claims, Defendents counter-claims dismissed.

Gerald Niznick

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

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This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Jun-03	Feb-04	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
03A468598		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Maurice Owens			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

"10/29/2010Order of Dismissal Without Prejudice (Judicial Officer: Bixler, James)Debtors: Sheldon Cloobeck (Defendant), Decatur Harmon LLC (Defendant), Stephen J Cloobeck (Defendant), Richard Cloobeck (Defendant)Creditors: Gerald A Niznick (Plaintiff), Reesa Niznick (Plaintiff)Judgment: 10/29/2010, Docketed: 11/09/2010"

Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jul-02	Feb-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A453516		Eighth Judicial District Court		
Reason/Charge				
Property Title Issue				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs Michael Huggins			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

Disposition: Entry Date & Time: 01/27/2003 @ 14:01 Description: SUMMARY JUDGMENT Debtor: Americana LLC Creditor: Niznick, Gerald Amount Awarded: $14000.00 Attorney Fees: $1000.00 Costs: $0.00 Interest Amount: $0.00 Total: $15000.00

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Jun-02	Jan-03	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02A452627		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick vs. Americana LLC, Paula Jones			Lawsuit	
Name of Business/Industry/Entity				
Gerald Niznick				

Provide explanation below:

Disposition: Entry Date & Time: 01/27/2003 @ 14:01 Description: SUMMARY JUDGMENT Debtor: Americana LLC Creditor: Niznick, Gerald Amount Awarded: $14000.00 Attorney Fees: $1000.00 Costs: $0.00 Interest Amount: $0.00 Total: $15000.00

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
May-03	Jan-10	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
03A468009		Eighth Judicial District Court		
Reason/Charge				
Civil Filing				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Gerald Niznick, Reesa Niznick vs Sheldon Cloobeck, Decatur H			Lawsuit	
Name of Business/Industry/Entity				
Gerald & Reesa Niznick				

Provide explanation below:

"10/29/2010Order of Dismissal Without Prejudice (Judicial Officer: Bixler, James)Debtors: Sheldon Cloobeck (Defendant), Decatur Harmon LLC (Defendant), Stephen J Cloobeck (Defendant), Richard Cloobeck (Defendant)Creditors: Gerald A Niznick (Plaintiff), Reesa Niznick (Plaintiff)Judgment: 10/29/2010, Docketed: 11/09/2010"

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Feb-08		NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
08A575522		Eighth Judicial District Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Implant Direct LLC vs Durango Warm Springs LLC			Lawsuit	
Name of Business/Industry/Entity				
Implant Direct LLC				

Provide explanation below:

Dispute over a lease, Implant Direct prevailed defendant settle with $50,000 donation to foundation.

Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

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This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Mar-14	Mar-17	NY	New York	New York
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
650908/14		SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK : IAS		
Reason/Charge				
Disagreement over sale of final shares of company and valuation.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Sybron Canada Holdings et al. v. Gerald A. Niznick et al.			Lawsuit	
Name of Business/Industry/Entity				
Implant Direct				

Provide explanation below:

The lawsuit was a disagreement between the parties over the key dates triggering the buyout of the Niznick remaining percentage of the partnership with Sybron Canada Holdings and the valuation of the remaining interest of Niznick. Counter suits included claims for damages and dispute over non-compete. Sybron Canada Holding's Inc. prevailed in their right to exercise their option to buy Dr. Niznick's remaining shares of Implant Direct and the court order that Sybron pay 75M plus 25M in interest. The result of Niznick vs. Sybron was non-compete set to expire 03/22/2022.

Dr. Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
May-06	May-06	CA	San Diego	San Diego
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
3:2006cv01135		Disagreement over Asset Purchase Agreement		
Reason/Charge				
Disagreement over Asset Purchase Agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Zimmer Dental Inc v. Niznick, et al			Arbitration	
Name of Business/Industry/Entity				
Zimmer Dental				

Provide explanation below:

The case of Zimmer Dental Inc. v. Gerald Niznick involved disputes over intellectual property, specifically dental implant patents and the advertising claims of innovation made by Zimmer Dental. The central issue arose after Zimmer Dental acquired Paragon Implant Company from Dr. Niznick in 2001, including several patents he had developed.

Dr Gerald Niznick
Original Signature (electronic, copies or stamps not accepted)

11/21/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gerald Niznick

Print Name (First, Last)

Dr Gerald Niznick

Original Signature (electronic, copies or stamps not accepted)

11/21/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Gerald Niznick, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Dr Gerald Niznick

Original Signature

11/21/24

Date

Subscribed and Sworn to before me this 21 day of NOV, 2024

Joseph Mina

Notary Public Signature

JOSEPH MINA
Notary Public - California
Los Angeles County
Commission # 2367367
My Comm. Expires Aug 19, 2025

(Seal)

10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stericycle, Inc.

Physical Address: 1655 Milan Drive

City: McCarran State: NV Zip: 89437

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 801-971-2042 Website: stericycle.com

Name of Designated Representative (DR): _____

Licensing Company Email: jbarr@stericycle.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	■ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Destruction only

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Walgreens
Address: 108 Wilmot Rd City: Deerfield State: IL Zip: 60015

Name: MED-Projects
Address: 1800 M St NW Ste 400 City: Washington State: DC Zip: 20036

Name: Cleveland Clinic Foundation
Address: 6801 Brecksville Rd City: Independence State: OH Zip: 44131

Name: Kaiser Permanente
Address: Bellflower Blvd City: Downey State: CA Zip: 90242

Section 4: Publicly Traded Corporation

State of Incorporation: Deleware
Parent Company (if any): N/A
Corporation Name: Stericycle, Inc.
Mailing Address: 2355 Waukegan Road
City: Bannockburn State: IL Zip: 60015
Telephone: 512-213-7089 Email:
Contact Person Name: Joel Barr

Date of SEC Registration: | SEC Registration Number: 4955 | Stock Exchange Symbol: SRCL

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stericycle, Inc.

Facility Name

Richard M. Moore

Print Name of Authorized Person Submitting Application

Richard M. Moore

Original signature of Authorized Person (copies or stamps not accepted)

06-25-2024

Date

Board Use Only	Date Received: 7/8/24	Amount: $1,000-00

Stericycle®
We protect what matters.

Officer List

Officers	**2355 Waukegan Road, Bannockburn, IL, 60015**
Cindy J. Miller	President and Chief Executive Officer
Janet H. Zelenka	Executive Vice President, Chief Financial Officer & Chief Information Officer
Richard M. Moore	Executive Vice President, North American Operations
S. Cory White	Executive Vice President and Chief Commercial Officer

Please see above list of the four executive officers with direct or indirect responsibility for, and oversight of, the permitted activity.

File Number 5617-389-7

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

STERICYCLE, INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON NOVEMBER 20, 1990, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 29TH *day of* MAY *A.D.* 2024 .

Authentication #: 2415003918 verifiable until 05/29/2025
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

Storey County
Community Development
PO Box 526
Virginia City, NV 89440

Account #: 211324

2025

County of Storey

BUSINESS LICENSE

Date Issued: 7/01/2024
Class: GENERAL
Expires: 6/30/2025

This License is Granted to:

STERICYCLE INC.
2355 WAUKEGAN RD.
BANNOCKBURN IL 60015

STERICYCLE INC., having paid the required Storey County business license fee(s) in the amount of $ 710.00 is hereby granted permission to transact business under the GENERAL license for the period 7/01/2024 through 6/30/2025 in conformance with and subject to the County Commissioners of Storey County, Nevada.

~ COUNTERSIGNED ~

Jennifer McCain
Storey County Comptroller

Pete Renaud
Building Official

THIS LICENSE MUST BE DISPLAYED IN A CONSPICUOUS PLACE

****NON-TRANSFERABLE****

Phone (775)-847-0966 ~ Fax (775) 847-0935 ~ buslic@storeycounty.org

Stericycle-Employees

FIRST NAME	LAST NAME	ID#
EFRAIN	ACEVEDO	[redacted]
KAYLIE	BALLARD	
BELA	BRUSZT	
Brown	Matthew	
KEITH	CALLAWAY	
JASMIN	CONE	
JOSHUA	COVELLO	
BRAXTON	CROWSON	
HOLLY	DAVIS	
CONNER	DUNN	
JARED	FOLEY	
TODD	HONEYCUTT	
EDUARDO	HERNANDEZ-FLORES	
KHRISTOPHER	KEATES	
DENNIS	KENNEDY	
ROSA	LOPEZ	
LOUIS	MARTINEZ JR	
RACHEL	NASON	
RIZZA	POCHOP	
OSWALDO	QUINONEZ	
FELICIA	RAMIREZ	
ADAM	SANCHEZ	
RUBEN	SOTO	
DASHAWN	SPENCE	
MICHAEL	THIGPEN	
JOSE	VALDIVIA	
VANCE	WALKER	
LEROY	WILLIAMS	
JESS	BARNETT	
SAM	DENNIS	
ANTHONY	GOMEZ	
BLAKE	NELSON	
SAMUEL	SMITH	
LOGAN	WATSON	
KEVIN	WASKIEWICZ	
MARK	JAMISON	
SAVANNAH	VALLES	
MICHAEL	DUPONT	

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 1-37556

Stericycle, Inc.

(Exact name of registrant as specified in its charter)

Delaware	36-3640402
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*

2355 Waukegan Road
Bannockburn, Illinois 60015
(Address of principal executive offices, including zip code)
(847) 367-5910
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	SRCL	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15-(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer" "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐
Smaller reporting company ☐	Emerging Growth Company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1b.☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒
The aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2023): $4,267,283,457.
On February 23, 2024 there were 92,567,104 shares of the Registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Items 10, 11, 12, 13 and 14 of Part III of this Report is incorporated by reference from the Registrant's definitive Proxy Statement for the 2024 Annual Meeting of Stockholders.



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Glossary of Defined Terms

Unless the context requires otherwise, the "Company", "Stericycle", "we", "us", or "our" refers to Stericycle, Inc. on a consolidated basis. The Company also uses several other terms in this Annual Report on Form 10-K, most of which are explained or defined below:

Abbreviation	Description
2021 Plan	2021 Incentive Stock Plan
2023 Form 10-K	Annual report on Form 10-K for the year ended December 31, 2023
Adjusted Income from Operations	Income from Operations adjusted for certain items discussed in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
AI	Artificial Intelligence
APHIS	Animal and Plant Health Inspection Service
ASU	Accounting Standards Update
CARES Act	U.S. Coronavirus Aid, Relief, and Economic Security Act enacted into law on March 27, 2020
CDC	U.S. Centers for Disease Control and Prevention
Clean Air Act	The Clean Air Act of 1970
COR	Cost of Revenues
COSO Criteria	Internal Control Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission
COVID-19	The global coronavirus disease 2019 outbreak, which the World Health Organization declared to be a pandemic
Credit Agreement	Credit Agreement dated September 30, 2021, First Amendment dated April 26, 2022, and Second Amendment dated June 15, 2023, among the Company and certain subsidiaries as borrowers. Bank of America, N.A., as administrative agent, swing line lender, a lender and a letter of credit issuer and the other lenders party thereto, as amended
Credit Agreement Defined Debt Leverage Ratio	As of any date of determination, the ratio of (a) (i) Consolidated Funded Indebtedness as of such date minus (ii) Unrestricted Cash as of such date to (b) Consolidated EBITDA (each as defined in the Credit Agreement) for the period of four fiscal quarters most recently ended on or prior to such date
Credit Facility	The Company's $1.2 billion credit facility due in September of 2026 granted under the terms of the Credit Agreement
CRS	Communication and Related Services (Divested December 2022)
DCF	Discounted Cash Flows
DEA	U.S. Drug Enforcement Administration. The DEA is a division of the DOJ. It is the federal agency which regulates the manufacture, dispensing, storage, and shipment of controlled substances including medications with human abuse potential
DOJ	U.S. Department of Justice
Domestic Environmental Solutions	Hazardous Waste Solutions and Manufacturing and Industrial Services (Divested April 2020)
DOT	U.S. Department of Transportation
DSO	Days Sales Outstanding as reported, defined as the average number of days that it takes a company to collect payment after revenue has been recorded, computed as the trailing twelve months of Revenues for the period ended, divided by the Accounts Receivable balance at the end of the period. Days Sales Outstanding, net of Deferred Revenues is similarly computed except Accounts Receivable balance is netted with Deferred Revenues.
DTSC	U.S. Department of Toxic Substances Control
EBITDA	Earnings Before Interest, Taxes, Depreciation & Amortization. Another common financial term utilized by Stericycle to analyze the core profitability of the business before interest, tax, depreciation and amortization
EHS	Environmental, Health and Safety
Enviri	Enviri Corporation, a Delaware Corporation, formerly known as Harsco Corporation
EPA	U.S. Environmental Protection Agency
ERISA	U.S. Employee Retirement Income Security Act of 1974, as amended by the Multi-Employer Pension Amendments Act of 1980
ERP	Enterprise Resource Planning
ESPP	Employee Stock Purchase Plan, which was approved by stockholders in May 2001 (as amended and restated in May 2017)
EU	European Union
Exchange Act	U.S. Securities Exchange Act of 1934
Expert Solutions	Recall and Return Services (Divested December 2020)
FACTA	U.S. Fair and Accurate Credit Transaction Act
FASB	Financial Accounting Standards Board
FCPA	U.S. Foreign Corrupt Practices Act
FCPA Settlement	FCPA Settlement with the Securities and Exchange Commission, the Department of Justice and Brazilian authorities of approximately $90.0 million and engagement of an independent compliance monitor for 2 years and self-reporting for additional year
FMCSA	U.S. Federal Motor Carrier Safety Administration
GDPR	General Data Protection Regulation
GILTI	Global Intangible Low-Taxed Income
GPO	Group Purchasing Organization
HIPAA	Health Insurance Portability and Accountability Act
HMIWI	Hospital, Medical, Infectious Waste Incinerator
IATA	International Air Transport Association
Indenture	Indenture, dated as of June 14, 2019 between the Company, the guarantors named therein and U.S. Bank National Association, as trustee
International	Operating segment including Belgium, France, Germany, Ireland, Luxembourg, Portugal, Spain, and U.K. The following countries were divested in 2023: Australia, Brazil, Republic of Korea, Romania, Singapore, and UAE

IRS	U.S. Internal Revenue Service
ISO	Incentive Stock Options
NOL	Net Operating Losses
North America	Operating segment including U.S., Canada and Puerto Rico
NOV	Notice of Violation
OSHA	U.S. Occupational Safety and Health Act of 1970
Other Costs	Represents corporate enabling and shared services costs, annual incentive and stock-based compensation
Pension Protection Act	Pension Protection Act of 2006
PFA	Pre-filing agreement with the IRS
PHMSA	U.S. Pipeline Hazardous Materials Safety Administration
Plan	401(k) defined contribution retirement savings plan
PPE	Personal Protective Equipment
PSU	Performance-based Restricted Stock Unit
Purchase Agreement	Stock Purchase Agreement, dated as of February 6, 2020, by and between Stericycle, Inc., and the Harsco Corporation (now known as Enviri) and CEI Holding LLC, a Delaware limited liability company and subsidiary of Harsco Corporation (now known as Enviri)
RCRA	U.S. Resource Conservation and Recovery Act of 1976
ROU	Right-of-Use
RSU	Restricted Stock Unit
RWCS	Regulated Waste and Compliance Services, a business unit that provides regulated medical waste services
S&P	Standard & Poor's
SEC	U.S. Securities and Exchanges Commission
Senior Notes	5.375% ($600.0 million) Senior Notes due July 2024 and 3.875% ($500.0 million) Senior Notes due January 2029
Series A	Series A Mandatory Convertible Preferred Stock, par value $0.01 per share
SG&A	Selling, general and administrative expenses
SID	Secure Information Destruction Services, a business unit that provides confidential customer material shredding services and recycling of shredded paper
SOFR	Secured Overnight Financing Rate - benchmark interest rate that replaced LIBOR
SOP	Sorted Office Paper
SQ Settlement	Small quantity medical waste customers class action settlement of $295.0 million
Tax Act	U.S. Tax Cuts and Jobs Act of 2017
Term Facility	Aggregate amount of commitments made by any lender under the terms of the Credit Agreement
Term Loans	Advances made by any lender under the Term Facility
TSA	Transition Services Agreement
UAE	United Arab Emirates
U.K.	United Kingdom
UPS	United Parcel Service, Inc.
U.S.	United States of America
USDA	U.S. Department of Agriculture
U.S. GAAP	U.S. Generally Accepted Accounting Principles

PART I

Disclosure Regarding Forward-Looking Statements

This document may contain forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. When we use words such as "believes", "expects", "anticipates", "estimates", "may", "plan", "will", "goal", or similar expressions, we are making forward-looking statements. Forward-looking statements are prospective in nature and are not based on historical facts, but rather on current expectations and projections of our management about future events and are therefore subject to risks and uncertainties, which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. Factors that could cause such differences include, among others, inflationary cost pressure in labor, supply chain, energy, and other expenses, decreases in the volume of regulated wastes or personal and confidential information collected from customers, and disruptions resulting from deployment of systems, disruptions in our supply chain, disruptions in or attacks on data information technology systems, labor shortages, a recession or economic disruption in the U.S. and other countries, changing market conditions in the healthcare industry, competition and demand for services in the regulated waste and secure information destruction industries, SOP pricing volatility or pricing volatility in other commodities, changes in the volume of paper processed by our secure information destruction business and the revenue generated from the sale of SOP, foreign exchange rate volatility in the jurisdictions in which we operate, changes in governmental regulation of the collection, transportation, treatment and disposal of regulated waste or the proper handling and protection of personal and confidential information, the level of government enforcement of regulations governing regulated waste collection and treatment or the proper handling and protection of personal and confidential information, the outcome of pending, future or settled litigation or investigations, charges related to portfolio optimization or the failure of acquisitions or divestitures to achieve the desired results, the obligations to service substantial indebtedness and comply with the covenants and restrictions contained in our credit agreements and Senior Notes, rising interest rates or a downgrade in our credit rating resulting in an increase in interest expense, political, economic, war, and other risks related to our foreign operations, pandemics and the resulting impact on the results of operations, long-term remote work arrangements which may adversely affect our business, restrictions on the ability of our team members to travel, closures of our facilities or the facilities of our customers and suppliers, weather and environmental changes related to climate change, requirements of customers and investors for net carbon zero emissions strategies, and the introduction of regulations for greenhouse gases, which could negatively affect our costs to operate, failure to maintain an effective system of internal control over financial reporting, as well as other factors described in our filings with the SEC, including the 2023 Form 10-K and subsequent Quarterly Reports on Form 10-Q. As a result, past financial performance should not be considered a reliable indicator of future performance, and investors should not use historical trends to anticipate future results or trends. We disclaim any obligation to update or revise any forward-looking or other statements contained herein other than in accordance with legal and regulatory obligations.

Item 1. Business

Overview

Company Overview

Stericycle, Inc., is a U.S. based business-to-business services company and leading provider of compliance-based solutions that protect people and brands, promote health and well-being and safeguard the environment. Through our family of brands, Stericycle serves customers in North America and Europe with solutions to safely manage materials that could otherwise spread disease, contaminate the environment, or compromise one's identity. To our customers, team members and the communities we serve, Stericycle is a company that protects what matters.

Segments

Our operating segments as of December 31, 2023, are North America and International.

Financial and other information related to our reporting segments is included in *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and *Part II, Item 8. Financial Statements and Supplementary Data*; *Note 17 - Segment Reporting*.

Services

Within our operating segments, our revenues are further broken down into these service categories:

Revenue Service Category	Services Offered
Regulated Waste and Compliance Services	• Biohazardous Waste Disposal (including Regulated Medical Waste, Sharps Waste Management and Disposal, Pharmaceutical Waste Management and Disposal, Chemotherapy Waste and Disposal, Controlled Substance Waste Disposal, Healthcare Hazardous Waste, and Integrated Waste Stream Solutions) • Compliance Solutions (including Steri-Safe® Compliance Solutions) • Specialty Services (including MedDrop™ Medication Collection Kiosks, Safe Community Solutions, SafeDrop™ Sharps Mailback Solutions, and Airport and Maritime Waste Services) • Medical Supply Store (including Sharps and disposable Biohazardous Waste Containers, Infection Control Supplies and Seal&Send Medication Mail Back)
Secure Information Destruction Services	• Secure information destruction and compliance solutions (including document, hard drive, and specialty destruction services) under the Shred-it® brand name which includes regular scheduled services (and processing onsite and offsite) and one-time services (including select, priority and express)

Revenues by service category for each of the operating segments were as follows:

In millions

	Year Ended December 31,	
	2023	2022
North America		
Regulated Waste and Compliance Services	$ 1,474.4	$ 1,468.8
Secure Information Destruction Services	781.4	794.3
Total North America Segment	2,255.8	2,263.1
International		
Regulated Waste and Compliance Services	301.4	329.4
Secure Information Destruction Services	102.1	112.2
Total International Segment	403.5	441.6
Total Revenues	$ 2,659.3	$ 2,704.7

See *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* for further information on changes in revenues.

Portfolio Optimization

We evaluate our portfolio of services on an ongoing basis with a country-by-country and service line-by-service line approach to assess long-term potential and identify potential business candidates for divestiture. Divestitures resulting from this evaluation may cause us to record significant charges, including those related to goodwill, other intangible assets, long-lived assets, and cumulative translation adjustments.

During 2023, we divested eight businesses, demonstrating significant progress in executing our portfolio optimization priority. These divestitures included an International container manufacturer joint venture, our businesses in Brazil, Singapore, Australia, and Republic of Korea, dental recycling business in the Netherlands, SID joint venture in the UAE, and our business in Romania for aggregate net proceeds of approximately $85 million.

On January 31, 2024, we acquired a southeastern U.S. regulated waste business for total consideration of approximately $16 million in cash and a promissory note. This acquisition is considered to be complementary to existing operations and aligns with our portfolio optimization strategy. The acquired business is anticipated to contribute less than 1% to the RWCS revenue service category for 2024.

For additional information regarding acquisitions and Divestiture losses (gains), net, including significant impacts of foreign currency translation adjustments, net, see *Part II, Item 8. Financial Statements and Supplementary Data; Note 3 – Acquisitions; Note 4 – Restructuring, Divestitures, and Asset Impairments* in the Consolidated Financial Statements.

Customers

Our service offerings appeal to a wide range of business customers. Our customers are primarily in the following industries: enterprise healthcare (i.e., hospitals, health systems, and non-affiliate hospitals; and national and corporate healthcare), practices and care providers (i.e., physician offices, surgery centers, veterinary clinics, nursing and long-term care facilities, dental clinics, clinics and urgent care, dialysis centers, and home health organizations), and pharmacy, lab and research centers. We also provide services to airports and seaports, education institutions, funeral homes and crematories, government and military, banks and professional services, and other businesses. While we manage large volumes of waste and other materials, the average volume per customer site is relatively small.

In 2023, no single customer accounted for more than 2% of our total revenues and our top ten customers collectively accounted for approximately 10% of total revenues. No single customer accounted for more than 2% of our total accounts receivable and our top ten outstanding customer balances accounted for approximately 8% of total accounts receivable. We have developed a strong and loyal customer base, with an estimated revenue retention rate of approximately 90% (based on our internal customer attrition analysis) and have been able to leverage these customer relationships to provide additional services.

As of December 31, 2023, Regulated Waste and Compliance Services are provided to customers in the U.S., Canada, Ireland, Portugal, Spain and the U.K. Secure Information Destruction Services under the Shred-it® brand are provided in the U.S., Belgium, Canada, France, Germany, Ireland, Luxembourg, the Netherlands, Portugal, Spain, and the U.K.

In the U.S. and elsewhere, the healthcare industry is evolving to meet competing demands for increased healthcare coverage of a growing and aging population and economic pressures to reduce healthcare costs. As a result of these dynamics, hospital networks are consolidating physician practices into their networks, independent practices are consolidating, while other customers are leveraging GPOs and delivering care through alternative sites of care, such as in-home, to reduce healthcare costs.

Our International RWCS operations generate most of their revenues from large account customers, such as hospitals, publicly funded healthcare organizations and National Trusts versus smaller customers which tend to be more profitable.

Facilities and Fleet

Our worldwide network includes a global fleet of approximately 5,200 route trucks, tractors, collection vans, and small duty vehicles. We operate out of approximately 396 facilities worldwide with properties both leased and owned as described below:

	Autoclave or Alternative Medical Waste Treatment	Medical Waste Incinerator Facilities	Secure Information Destruction Processing	Transfer Stations (RWCS and SID)	Other Locations and/or Administrative Facilities	Total Facilities
North America	49	9	90	139	10	297
International	22	9	15	38	15	99
Total	71	18	105	177	25	396

We are headquartered in Bannockburn, Illinois.

Our Key Business Priorities

Following its founding in 1989, Stericycle grew rapidly through acquisitions as the regulated waste industry developed. Growth from regulated waste acquisitions helped us achieve scale of infrastructure, route density and a leadership position in many of the markets we serve. We also leveraged acquisitions to enter new regional and international geographies and added additional services to our portfolio, including the Secure Information Destruction business in 2015. As we grew and evolved, we operated without centralization and the efficiencies that come from an integrated, modern structure and associated information systems until we shifted our focus to our five key business priorities in 2019.

- ***Quality of revenue*** – We have been executing against our foundational initiatives we launched to drive revenue quality and are executing on: (i) expanding service penetration, (ii) improving customer implementation velocity, and (iii) deepening customer partnerships by developing enhanced solutions.
- ***Operational efficiency, modernization, and innovation*** – We have been executing on our foundational initiatives we launched to drive operational efficiency, modernization and innovation and are executing on: (i) infrastructure and system modernization, (ii) fleet replacement and route and long-haul network improvements and (iii) SafeShield container rationalization and modernization.
- ***ERP implementation*** – We successfully deployed the North America ERP to the U.S. RWCS business in the third quarter of 2023. Almost all of our U.S. team members are now leveraging the new technology. We continue to observe improvement in our team members' performance as they leverage the technology and data flow. We commenced activities for the international system modernization in 2022.
- ***Portfolio optimization*** – We expect to continue evaluating opportunities to further optimize our portfolio through a combination of asset rationalizations and strategic accretive tuck-in acquisitions, which streamline our portfolio of businesses and allow us to focus more deeply on our core businesses. 2023 divestitures primarily included an International container manufacturer joint venture in Spain; our businesses in Brazil, Singapore, Australia, and Republic of Korea; dental recycling business in the Netherlands; SID joint venture in the UAE; and our business in Romania for net proceeds of approximately $85 million.
- ***Debt reduction and leverage improvement*** – We have reduced total net debt to $1.27 billion as of December 31, 2023. In the second quarter of last year, we successfully achieved our goal of reducing our debt leverage below 3 times and have continued to maintain our debt leverage target, finishing 2023 with a debt leverage ratio of 2.85 times.

For further details, refer to *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and *Part II, Item 8. Financial Statements and Supplementary Data; Note 3 – Acquisitions, Note 4 – Restructuring, Divestitures, and Asset Impairments,* and *Note 9 – Debt.*

Regulated Waste and Compliance Services

Collection and Transportation

The collection process for regulated waste streams begins at the customer location with waste segregation. To assure regulatory compliance, we educate our customers and will not accept material from customers unless it complies with our waste acceptance protocols and is properly stored or packaged in containers that we have either supplied or approved and is appropriately labeled.

Our team members then collect containers at the customer location via our fleet of vehicles. The majority of collected waste is then transported directly to one of our processing facilities or to one of our transfer stations until it's transported to a processing facility. Our use of transfer stations in a "hub and spoke" configuration improves the efficiency of our collection and transportation operations by expanding the geographic area that a particular processing facility can serve, thereby increasing the utilization of the facility and the volume of waste that it processes.



Processing and Disposal of Regulated Waste

Upon arrival at a processing facility, containers or boxes of regulated waste undergo a quality control process to verify that they do not contain any unacceptable substances. Any container or box that is discovered to contain unacceptable waste goes through a corrective action process which could include redirecting the waste, returning the waste to the customer and/or notifying the appropriate regulatory authorities. From there, regulated waste is processed using one of several treatments or processing technologies, predominantly at one of our facilities:

- ***Autoclaving:*** Autoclaving is the primary method of regulated waste treatment. This process relies on steam at high temperature and pressure to kill pathogens and render materials non-infectious.
- ***Alternative Technologies***: We use several different non-incineration alternatives to autoclaves, predominantly outside of the U.S. The processes used by these technologies are similar, as the regulated waste is heated to a specified temperature for a required time to kill the pathogens and render materials non-infectious. This is not always under pressure. Depending on local requirements, the waste may be shredded before or after treatment to render it unrecognizable.
- ***Incineration:*** While Stericycle strives to use alternative, non-incineration methods for treating medical waste, incineration remains a regulatory requirement and/or a best practice in certain geographies or for certain types of medical waste that need to be chemically destroyed. Incineration burns regulated waste at elevated temperatures and reduces it to ash. Incineration reduces the volume of waste, and it is the recommended treatment and disposal option for some types of regulated waste such as anatomical waste, residues from chemotherapy procedures and non-hazardous pharmaceutical waste. Air emissions from incinerators can contain certain byproducts that are subject to federal, state and in some cases, local regulation. In some circumstances, the ash byproduct of incineration may be regulated.

Upon completion of the treatment process, the resulting waste or incinerator ash is transported for disposal in a landfill owned by unaffiliated third parties.

In several of our incineration facilities, we use different types of waste-to-energy solutions as part of our processes. Stericycle has four incinerators with steam turbines that can generate electricity and reduce the amount of power required from utilities at each site. In the U.K., several of our incinerators export steam to hospitals, where they are co-located, to be used for facility or hot water heating, steam sterilization, and/or laundry services. Similar to exported steam, two of our U.K. incinerators export hot water to nearby hospitals. In the U.K. and Ireland, after medical waste has gone through the alternative treatment process, it is sent for beneficial reuse. This treated waste is sent to cement producers and used as an alternative fuel for cement kilns.

Secure Information Destruction

We leverage a combination of off-site and on-site document destruction methods for one-time and recurring paper shredding. In North America in 2023, approximately 72% of collected documents for secure destruction were sent off-site to geographic consolidating shredding facilities for secure destruction. The remainder of collected documents are shredded on-site with shredding equipment in our vehicles. For both methods, our service offerings leverage cross-cut shredding technology to enhance the security level of destruction and can provide secure chain-of-custody and Proof of Service.

Shredded paper is then sold as SOP for recycling. SOP consists of paper typically generated by offices that contains primarily white paper. White paper is a higher value recyclable than mixed paper, which mainly consists of newspapers or magazines. In 2023, Stericycle collected approximately 462,000 tons of SOP for recycling, a decrease of 11.7% compared to 2022 of approximately 523,000 tons. After excluding the impact of divestitures, we collected approximately 453,000 tons and approximately 500,000 tons in 2023 and 2022, respectively. This resulted in a decline in SOP, excluding divestitures, of approximately 47,000 tons or 9%. During 2023, the average annual SOP price was $174 per ton, as reported by Fastmarkets, a decrease of 26.0% compared to 2022.

Our Business Model and Key Business Attributes

Regulated Business-to-Business Operations

We focus on providing business-to-business services in areas of operations that are highly regulated. By helping our customers maintain compliance with complex regulations, we protect people and brands, promote health and well-being and safeguard the environment. Governmental legislation and regulation require the proper handling and disposal of items such as regulated waste and personal confidential information. Regulated waste can be defined as any material subject to government-imposed guidelines for handling the material for transportation or disposal.

- ***Regulated Medical Waste:*** Regulated medical waste generated from procedures including any items saturated with blood or other potentially infectious materials (OPIM), such as bandages, gauze, or PPE, are considered regulated medical waste.
- ***Trace Chemotherapy Waste:*** Chemotherapy waste includes empty chemo drug vials, syringes and hypodermic needles, spill kits, IV tubing and bags, contaminated gloves and gowns, materials from spill cleanups, or bodily fluids/waste.
- ***Pathological Waste:*** Pathological waste such as human or animal tissues, body parts, and surgical specimens (decanted of formaldehyde, formalin, or other preservatives) are packaged separately.
- ***Sharps Waste:*** Sharps waste such as needles, scalpels, blades, and pipettes that have come in contact with blood, body fluids, or microorganisms.
- ***Pharmaceutical Waste:*** Pharmaceutical waste that may be hazardous or nonhazardous and consists of expired, recalled, or otherwise unused pharmaceuticals.
- ***Controlled Substances Waste:*** Controlled substances waste includes unused, unwanted, or expired pharmaceutical controlled substances.
- ***Healthcare Hazardous Waste:*** Healthcare hazardous waste includes prevalent and well-known waste streams and other wastes generated in smaller quantities that require proper attention, such as flammable liquids, xylene, formalin, aerosols, and universal waste.
- ***Solid Waste and Recycling:*** Solid waste and recycling services.
- ***Maritime Waste:*** Airport and seaport generated waste including gray water, black water, bilge water, sludge, solid waste, recyclable solid waste, RCRA hazardous waste, APHIS waste, and universal waste.
- ***Personal Confidential Information:*** Documents and e-media containing protected healthcare information, financial information, or other confidential information.

Growing Markets

The demand for our services, especially our core services of regulated waste and compliance and secure information destruction, are expected to grow or have historically grown. This growth is driven by multiple factors:

- ***Aging Population and Demographic Changes:*** The average age of the population in the countries in which we operate is rising, driving increases in healthcare demand and the quantity of regulated wastes generated.
- ***Enforcement of Waste Regulations:*** We operate in a highly regulated business where penalties for violations can be costly and high profile, thereby impacting our customers' overall reputation. We believe that many businesses are either unaware of the need for proper training of employees or of applicable regulatory requirements or understaffed or lack the expertise to comply with the regulations, and we seek to help businesses fill this gap.
- ***Regulation of Privacy and Information Security and Concerns over Data Breaches:*** The secure information destruction total addressable market has been driven, in part, by the need for compliance with increasing government regulation and increasing general concern with privacy and information security. Recent regulatory changes reflecting this increased regulatory focus include the European GDPR; California, Colorado, and Virginia's comprehensive consumer privacy legislation; and Canada's Personal Information Protection and Electronic Documents Act. Moreover, the majority of states are working on comprehensive consumer privacy legislation.
- ***Increased Business Focus on Sustainability:*** Businesses continue to realize that a focus on sustainability is increasingly essential to operating efficiently and meeting the increasing demands and expectations of customers and stakeholders for environmental responsibility. Such pressures are driving proper disposal of pharmaceuticals, recycling efforts, shred-all policies for paper and other initiatives supported by our services.

Stable and Recurring Customer Needs Supported by Long-term Contracts

The services we provide most often require service on a routine and scheduled basis. The majority of our customer relationships include long-term contracts ranging from three to five years in length. We have developed a strong and loyal customer base, with a revenue retention rate of approximately 90% (based on our internal customer attrition analysis) in 2023.

Established Network of Processing and Transportation Locations

Our infrastructure network results in an expansive operational network with alternate transportation, treatment, destruction, and recycling options for our customers. The scale of our network also provides us the ability to be the single-source provider for customers with multiple locations across the country and gives us the flexibility to quickly redirect services or operations to another location if the need arises due to severe weather, power outages, or other disruptions.

Our goal is to optimize our facilities with a strategic and standardized operating model. We are analyzing processing capabilities, plant and transportation equipment needs, team member requirements, and potential customer implications or benefits. This planning process also provides opportunities to focus on reducing our environmental impact by optimizing our transportation network to reduce miles driven and overall greenhouse gas impact. We anticipate that modernizing our plant equipment with new efficient technology will also lessen our overall energy consumption per operating cycle. Over the past three years, we have opened several new greenfield autoclave facilities (New Jersey, California, Ireland, and United Kingdom) and completed over 20 upgrade projects, including improvements to autoclaves, shredders, washers and enhanced conveyance, and sharps processing. These new and improved facilities and upgrades represent the initial steps in modernizing our global facility network which we plan to expand in future periods. In 2022, we began constructing a commercial HMIWI in Nevada that we expect to complete in the first half of 2024 and begin testing.

Routing Logistics

While we manage large volumes of waste and secure information for destruction, the average volume per customer site is relatively small and the resulting revenue per stop is low. As such, route logistics and route efficiency are a core focus. Our transportation network provides us with an advantage compared to our competition in many of the markets we serve. Additionally, we have continued to focus on route density and optimization at both the individual truck and geographic market level. By optimizing locations of our new facilities and executing our transportation and long-haul plan, we are now driving fewer miles per month, on average. We expect that the North America ERP implementation will continue to provide greater visibility to data which will continue to enable additional routing and operational efficiencies.

Industry Leadership and Expertise

Based on our infrastructure and revenues, we maintain a leadership position across many of our services lines, including regulated waste and secure information destruction. We employ experienced team members who have a deep understanding of the industries they serve, the regulatory climate and the evolving needs of our customers. We collaborate regularly with a wide range of stakeholders and interest groups. Starting in 2020, the Company took a leadership position related to the management of COVID-19 pandemic waste, supporting our customers and providing industry expertise regarding the effective management of COVID-19 waste. In 2014, we were tasked by the DOT and CDC to dispose of waste from the Ebola outbreak. We proactively work with organizations like the CDC, DEA, EPA, OSHA and many other government and regulatory bodies, including law enforcement. Our experts are frequent speakers at hospital networks and industry trade associations and actively engage in numerous community meetings each year.

Human Capital Management

Workforce Overview

As of December 31, 2023, our workforce is over 13,500 team members, with 97% of them employed full-time. We engage approximately 1,300 global contingent workers, supplementing our team to fill temporary positions or as a part of a temporary-to-permanent recruiting program. The year over year decrease in team members was primarily attributed to divestitures and workforce management through careful hiring, attrition, and targeted workforce reduction.

Our 2023 voluntary turnover rate, excluding turnover due to divestitures, averaged approximately 22%. In 2022 our voluntary turnover rate, excluding turnover due to divestitures, averaged approximately 28%.

As of December 31, 2023, 10% of our total global workforce was covered by collective bargaining agreements or works councils. There are 19 collective agreements in the U.S. and Canada, covering approximately 720 team members or 7% of our North American workforce. Approximately 680 team members outside North America are covered by collective bargaining agreements or works councils. We engage in good faith bargaining with the works councils and unions that represent our team members.

Diversity and Inclusion

At Stericycle, embracing the diversity and inclusion of our workforce is one of our core values. In 2023, approximately 22% of our global workforce were women, including 33% in middle management and 29% in leadership positions (directors and above). The racial and ethnic diversity of our U.S. workforce was comprised of White, 45%; Black or African American, 27%; Hispanic/Latino, 22%; Multi-Ethnic or Other, 4%; and Asian, 2%; with 55% of our team members identifying as minorities.

During 2023, 67% of U.S. new hires and 51% of internal promotions were from federally designated racial or ethnic minority categories. We hired approximately 180 team members during 2023 who identified as U.S. veterans.

We believe our seven employee resource groups (ERGs) help drive engagement and representation and support team members who are Women, Black and African American, Latinx, Veterans, members of the LGBTQ+ (lesbian, gay, bisexual, transgender, and queer) community, young professionals, and team members and their family members who have disabilities. We routinely leverage our ERGs to address important social topics with our team members through "Let's Talk About It" video discussion, "FIERCE Cafe", and other internal discussions. Additionally, during 2023, our ERGs provided educational communications to our team members; hosted speaker events; led company celebrations for Black History Month, Hispanic Heritage Month, Pride Month, Veterans Day, and other days of diversity awareness or celebration; and provided mentoring programs for Women, Black and African Americans, and Veterans. We also launched an Unconscious Bias training program in 2023.

Compensation

In 2023, we continued our market-based compensation analyses which included pay equity analysis and identification of potential pay gaps. We independently consulted with third-parties on our pay practices and policies to ensure equitable pay across employee groups. We remain committed to a routine review of the competitiveness and equity of our team members' compensation, with the next detailed analysis occurring in 2025. Additionally, we continue to monitor and comply with state laws around pay transparency.

Safety

At Stericycle, a commitment to safety is one of our core values. We focus on a comprehensive safety program to protect our team and the communities in which we operate and drive our safety performance.

In 2023, our safety improvement journey included a comprehensive focus on developing centralized procedures, processes and monitoring as well as investment in new training programs to increase safety awareness. During 2023, our safety program included:

- a global expansion of our comprehensive defensive driving program;
- a continuation of our Corporate Integrated Audit Program, ensuring compliance with our policies and procedures as well as applicable laws and regulations;
- a monthly safety global coaching and communications program; and
- a weekly published Safety Exchange with themed procedures and best practices.

To further our safety objective and measure our progress, we track key safety metrics, Total Recordable Incident Rate (TRIR), which is calculated by multiplying the total number of recordable workplace injuries or illnesses by 200,000 and dividing by the total hours worked ((Injuries x 200,000) / Hours), and Severe Vehicle Incident Rate (SVIR), which is calculated by multiplying the total severe vehicle incidents by 200,000 and dividing by the total hours worked ((Injuries x 200,000) / Hours), which are components of team member total compensation.

Our Operating Environment

Competition

The industries and markets in which we operate are highly competitive on pricing and barriers to entry are low. Our competitors consist of many different types of service providers, including national, regional and local companies. Some of these companies provide only a portion of the services of Stericycle - for example, just collection and transportation, but not treatment of regulated waste.

In the regulated waste and secure information destruction industries, another source of competition is on-site management. For regulated waste, some large-quantity waste generators, particularly hospitals, may choose an onsite autoclave or other treatment process. For secure information destruction, many businesses may choose to use small, on-site shredders for their documents. In both regulated waste and secure information destruction, we believe there is no other competitor in North America with Stericycle's overall scale, breadth of services, national transportation network and comprehensive treatment network in our two core businesses.

Governmental Regulation

Stericycle's RWCS and SID services, are subject to numerous regulations, which may evolve over time. We are subject to substantial regulations enacted and enforced by governments within the U.S. and the international jurisdictions in which we conduct operations. In many countries, there are multiple regulatory agencies at the local and national level that oversee our customers and/or our services. The regulatory requirements with which we must comply vary from jurisdiction to jurisdiction. The laws governing our domestic and international operations generally consist of statutes and regulations concerning environmental protection; employee and public health and safety; transportation; document destruction and management; data privacy; ethical business conduct; and the management of regulated waste streams, including regulations that govern the definition, generation, segregation, handling, packaging, transportation, treatment, storage and disposal of regulated waste.

This regulatory framework imposes a variety of compliance requirements, including requirements to obtain and maintain government permits or other authorizations. We maintain governmental permits, registrations and licenses to conduct our business throughout the jurisdictions in which we operate. Our permits vary by jurisdiction based upon our activities within that jurisdiction and on the applicable laws and regulations of that jurisdiction. These permits grant us the authority to, among other things, construct and operate transfer and processing facilities; transport regulated waste within and between relevant jurisdictions; and handle particular regulated substances. Our permits, registrations and licenses may be subject to modification or revocation by the issuing authority and, in some jurisdictions, are subject to periodic renewal. Permit issuance or renewal may also be subject to public participation.

Various U.S. and international laws and regulations related to data privacy and the protection of confidential information also apply to Stericycle's RWCS and SID services, including HIPAA and the CCPA in the U.S. and the GDPR in Europe. In addition, laws governing ethical business practices apply to our business including, but not limited to, the FCPA, and the U.K. Bribery Act. These laws may apply to our business on both a global and local basis and ban unethical behavior such as the payment of bribes to government officials for the purpose of gaining an improper business advantage, improper maintenance of our books and records, as well as other financial transparency requirements.

Environmental Protection

Our business is subject to extensive and evolving environmental regulations in the geographies in which we operate. Generally, the environmental laws that we are subject to regulate the handling, transportation, treatment and disposal of waste, the release or potential release of hazardous substances into the environment, the discharge of pollutants into waterways and the emission of pollutants into the air. The principal environmental laws that govern our operations in the U.S. are the federal Clean Air Act and Clean Water Act, in addition to state laws and regulations governing regulated waste. Examples of environmental laws applicable to our international operations include the Waste Framework Directive, Environmental Liabilities Directive, Industrial Emissions Directive and the Shipments of Waste Regulations in the EU, and the Canadian Environmental Protection Act and related regulations in Canada.

Climate and Sustainability

Consistent with our Company's commitment to sustainability and environmental protection, we have published our 2023 Corporate Social Responsibility Report (CSRR), providing details on our environmental, social and governance (ESG) performance. The information in this report can be found at https://investors.stericycle.com but it does not constitute a part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

Employee Health and Welfare

We are subject to numerous regulations promulgated to protect and promote employee health and welfare through the implementation and enforcement of standards designed to prevent illness, injury and death in the workplace. The primary U.S. federal laws relating to employee health and welfare applicable to our business are overseen by OSHA, which establishes specific employer responsibilities including implementing engineering controls, administrative controls, training, policies and programs to comply with the regulations, and recordkeeping and reporting, all to ensure a safe workplace. Various OSHA standards apply to almost all aspects of our operations and govern such matters as exposure to bloodborne pathogens, hazard communication, and PPE.

Examples of employee health and welfare laws applicable to our international operations include the European Framework Directive on Safety and Health at Work (Directive 89/391 EEC) and various provisions of the Canada Labour Code and related occupational safety and health regulations in the provinces and territories of Canada.

Transportation

Various laws regulating the transportation of waste and other potentially hazardous materials also apply to the services we provide. In the U.S., the DOT has established regulations which deal with two different aspects of transportation: hazardous materials transport and safety in transportation. These regulations are defined within the PHMSA and the FMCSA. We are regularly subject to roadside inspections. These inspections have a cumulative effect on our compliance history and require us to remain in good standing so as not to jeopardize our permits.

Examples of transportation laws applicable to our international operations include the Directive on the Inland Transportation of Dangerous Goods in the EU, and the Transport of Dangerous Goods Act, and related regulations in Canada, and globally the International Maritime Dangerous Goods Code, and the IATA Dangerous Goods Regulations.

Controlled Substances

Our service offerings for the collection, treatment, and disposal of controlled substance waste, from both the healthcare industry and individual consumers, are subject to numerous laws and regulations governed by various regulatory agencies, including the DEA. These regulations typically require our facilities to obtain licenses or registrations, and meet other certain requirements for approval to collect, transport, treat and dispose of controlled substances. These regulations have very prescriptive requirements for security, recordkeeping and reporting. Like other regulatory schemes, registrations/licenses must be kept current, and facilities may be subject to inspection or enforcement.

U.S. and Foreign Local Regulation for Waste Management

We conduct business in all 50 U.S. States and Puerto Rico. Because the U.S. EPA does not regulate medical waste at the federal level, each state has its own regulations related to the handling, treatment and storage of regulated medical waste. Many states have followed requirements similar to the Medical Waste Tracking Act of 1988 or have placed regulated medical waste regulations within solid waste regulations. Regulated Garbage (i.e., international food waste) is another waste stream that is subject to unique regulatory requirements that are promulgated and enforced by the USDA and U.S. Customs and Border Protection. The USDA typically inspects our facilities receiving Regulated Garbage waste on a quarterly basis.

In each state where we operate a processing facility or a transfer station, we are required to comply with varying state and local laws and regulations, which may also require a specific operating plan. In addition, many local governments have ordinances and regulations, such as zoning or wastewater regulations, that affect our operations. Similarly, our international operations are subject to regulations enacted and enforced at the provincial, municipal, and local levels of government in addition to the national regulations with which we must comply.

Insurance and Self-Insurance

The regulated waste industry involves potentially significant risks of statutory, contractual, tort and common law liability claims. Potential liability claims could involve, for example: cleanup costs, personal injury, damage to the environment, employee matters, property damage including fleet vehicles, or alleged negligence or professional errors or omissions in the planning or performance of work. We also could be subject to fines or penalties in connection with violations of regulatory requirements.

We carry insurance that include property, workers compensation, general liability, employer's liability, pollution liability, privacy and security liability, cyber-liability, directors and officers and miscellaneous professional services errors and omissions coverage. We also carry umbrella policies that cover general liability, automobile and employers' liability. We regularly evaluate other lines of coverage to respond to specific business needs but consider our current insurance coverage to be sufficient to meet regulatory as well as customer requirements and to protect our employees, assets and operations.

Patents, Trademarks and Proprietary Rights

Stericycle holds a number of patents or applications in the U.S., Canada, the U.K., and Europe for technologies related to its business, including our patented innovation, SMS Revolution, which modernizes our processing of sharps, and innovations for the recovery of reusable medical devices in a sharps container, various waste container assemblies, a lockable mounting bracket for use with a waste container assembly, and a three-stage shredder.

We own federal registrations for a number of trademarks/service marks including Stericycle®, Shred-it®, We Protect What Matters®, SafeShield®, Steri-Safe®, SafeDrop®, Artech®, Community Shred-it®, Making Sure it's Secure®, Virtual Compliance Partner®, the Stericycle logo service mark consisting of a nine-circle design and the Shred-it logo. We also hold international registrations for Stericycle and the Stericycle and Shred-it logos, among others.







11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

4

Section 1: General Information

First: Amanda Middle: May Last: Morend

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Elko State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Signature of Program Director: _____

Section 3: Employment Information

Pharmacy Name: CVS Health #8801 License #: PH00641

Address: 550 W. Idaho St

City: Elko State: NV Zip: 89801

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: Edward C. Reed High Graduation Date OR Date GED obtained (mm/yy): 6/1995

Address: 1350 Baring Blvd

City: Sparks State: NV Zip: 89436

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	X	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.	Initials AM	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2008	2009	NV	Reno	Washoe
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Washoe County		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below: *I no longer have any case info, it does not show up on any search

Successfully completed Washoe County drug diversion sometime in 2009. Was actively using methamphetamens back then and I cashed a check and got in trouble for it. I paid everything back, successfully graduated the drug diversion program as well as Probation. I have not been in trouble since then, and have turned my life around. I am now a Store Manager at CVS health and would like to further my career with them and to be able to better help our Customers/Patients by being able to help as much as I can in their lives. This was expunged off of my record.

Amanda Moore — 10/29/2024

Original Signature (electronic, copies or stamps not accepted) — Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Amanda Moreno

Print Name

Amanda Moreno

Original Signature (electronic, copies or stamps not accepted)

10-29-2024

Date

Board Use Only	Date Received: 11/4/24	Amount: 850-MO19-69116956

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (03/17/2023)

Y

Section 1: General Information

First: LUCIA Middle: MAGALI Last: CRUZ

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: North Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Section 3: Employment Information

Pharmacy Name: Walgreens License #: PHN 01519

Address: 1445 W. Craig Rd. Ste 100

City: N. Las Vegas State: NV Zip: 89032

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	
High School Name: PARK West High School Graduation Date OR Date GED obtained (mm/yy): 04/02		
Address: 1540 W Second St.		
City: Pomona State: CA. Zip: 91766		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	**Initials** JC	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/08/14	04/24/16	CA.	San Bernardino	San Bernardino

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
[redacted]	San Bernardino Superior Court

Reason/Charge	
HS11377(A)-M: Poss Dangerous Drug/Cntrl Subs	
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**
The People of the State of California	
Name of Business/Industry/Entity	

Provide explanation below:

I was initially stopped by police as a traffic stop due to my license plates tags being expired. I also had an expired/suspended Drivers License and no insurance. I was giving a friend a ride and ~~as~~ as we were being pulled over he handed me a little bag and asked to hide it. I got scared, panicked and stuffed in my bra. Because I was being arrested for the traffic violations and was going to be transported to jail; I told the officer of what I had in my possession, I didn't want to get in more trouble. I have since removed myself from people that are no good and eventually saved enough money to move out of state and pretty much have no contact with anyone other than close friends and family. I have realized one mistake would affect long term and choose not to make another.

Lucy Cruz
Original Signature (electronic, copies or stamps not accepted)

7/8/2024.
Date

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box):	**Required documents to be submitted with your application.**
☐ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☐ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a signed affidavit by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☒ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

LUCY CRUZ
Print Name

Lucy Cruz
Original Signature, no copies or stamps accepted

1/20/2024
Date

Board Use Only	Date Received: _____	Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PTT: Lucy Cruz
PTT License #: PT 28258
Pharmacy Manager Name: Rebecca Richards
Pharmacy Manager License #: 14377
Name of Pharmacy: Walgreens
Pharmacy License #: PHN01519
Pharmacy Address: 1445 W. Craig Rd Ste 100
City: N. Las Vegas
State: NV
Zip: 89032
Time period PTT employed (mm/yy-mm/yy): 11/22 – 03/24

I certify to the Board that the above-named PTT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Filling prescriptions, typing prescriptions, billing insurance ringing up prescriptions

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☒ Yes ☐ No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

Rebecca Richards
Print Name (First, Last)

Rebecca Richards
Original Signature of Managing Pharmacist, no copies or stamps accepted

3-22-24
Date

Board Use Only	Date Received:

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary (TSB1402438) 07/03/2024 20:34:08

TSB1402438

The People of the State of California vs. LUCY LIRA

Case Information

Case Type:	Misdemeanor
Case Number:	[redacted]
Citation Number:	0992141
Filing Date:	11/17/2014
Case Status:	Closed
Court Location:	San Bernardino
Judicial Officer:	
Next Hearing:	

Case Flags

Demographic Information

Date of Birth	
Race:	
Sex:	
Height:	#Error
Weight:	
Hair Color:	
Eye Color:	
DL #:	
FBI #:	
State ID:	

Address

Street Name:	
City:	
State:	
Zip:	

Alias(s) / Nickname(s)

LIRA, LUCY MAGALY

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary (1[redacted]) 07/03/2024 20:34:08

Cross Reference

Parties

Type	Name	Status
Defendant	LIRA, LUCY MAGALY	Active
Plaintiff	The People of the State of California	Active

Attorneys

Representing	Name
LUCY MAGALY LIRA	**Public Defender**

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary ([redacted] 07/03/2024 20:34:08

Events

File Date	File Type	Filed By
4/26/2016	Plea Bargain Agreement Filed	
4/12/2016	Defendant Arraigned on Citation	
4/12/2016	Pay court appointed counsel reg. fee to Central Collections.	
4/12/2016	Time runs:	
4/12/2016	Agreement To Appear Filed	
4/12/2016	Defendant Advised of Rights	
4/12/2016	Public Defender Appointed	
4/12/2016	Revenue Recovery notified	
3/22/2016	Defendant To Report To Department	
12/1/2014	Legacy Minutes	
Comment:	WCB, C-COMMISSIONER CLERK: V0290-DIANNA AGUILAR - APPEARANCES DEFENDANT NOT PRESENT. - PROCEEDINGS ACTION CAME ON FOR ARRAIGNMENT COMPLAINT AMENDED TO ALLEGE NEW COUNT 005, A VIOLATION OF M40508A VC. DEFENDANT FAILS TO APPEAR AS PREVIOUSLY ORDERED. OR REVOKED. - - CUSTODY STATUS CASE CUSTODY - FUGITIVE ========== MINUTE ORDER END ========== 0	
11/17/2014	New Filed Case	
11/17/2014	Citation Approved For Filing By The District Attorney	
Comment:	CITATION APPROVED FOR FILING BY THE DISTRICT ATTORNEY	

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary ([redacted]

07/03/2024 20:34:08

Hearings

Department	Judge	Court Reporter	Type	Date	Time	Result
Department S7 - SBJC	Bradley, W. Charles		Pretrial: TR 5-27-16	4/26/2016	8:30AM	Held
Department S7 - SBJC	Bradley, W. Charles		Arraignment	4/12/2016	9:45AM	Held
	Bradley, W. Charles		Arraignment	12/1/2014	1:30AM	Held

Arrest Information

Count	Statute	Report Num	Agency	Arrest Date	Booking Num	Booking Agency	Jurisdiction

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary [redacted] 07/03/2024 20:34:08

Charges Disposition & PLEAS

Count	Date	Details	Citation #	Jurisdiction
1	10/8/2014	VC4000(A)(1)-I: Veh Registration Fees Due	0992141	San Bernardino
	Plea:	4/12/2016 - Not Guilty		
	Dispositions:			
	Date	**Disposition**		
	4/26/2016	Dismissal/Stricken - PC1385 Interest of Justice		
2	10/8/2014	VC14601(A)-M: Driving W/Suspended/Revoked Driver'S License	0992141	San Bernardino
	Plea:	4/12/2016 - Not Guilty		
	Dispositions:			
	Date	**Disposition**		
	4/26/2016	Dismissal/Stricken - PC1385 Interest of Justice		
3	10/8/2014	VC16028(A)-I: No Evidence Of Finan Resp/Veh	0992141	San Bernardino
	Plea:	4/12/2016 - Not Guilty		
	Dispositions:			
	Date	**Disposition**		
	4/26/2016	Dismissal/Stricken - PC1385 Interest of Justice		
4	10/8/2014	HS11377(A)-M: Poss Dangerous Drug/Cntrl Subs	0992141	San Bernardino
	Plea:	4/12/2016 - Not Guilty		
	Dispositions:			
	Date	**Disposition**		
	4/26/2016	Dismissal/Stricken - PC1385 Interest of Justice		
5	10/8/2014	VC40508(A)-M: Failure To Appear (Dmv Hold)	0992141	San Bernardino
	Plea:	4/12/2016 - Not Guilty		
	Dispositions:			
	Date	**Disposition**		
	4/26/2016	Dismissal/Stricken - PC1385 Interest of Justice		

Financial Transactions

Total	**$0.00**	**Total Balance:**	**$0.00**

Court Access Portal

Superior Court of California - County of San Bernardino

Case Summary (TSB1402438) 07/03/2024 20:34:08

Date	Charges	Payments	Credits
Total	$0.00	$0.00	$0.00

Bonds

Type	Description	Posted Date	Set Date	Amount

Related Cases

Case Number	Case Type	Case SubType	Description	Comments

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: John Middle: Henry Last: Vennochi

Date of Birth [redacted] SSN or ITIN [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: DMD Practitioner License #: 2510 Specialty: General Dentist

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): College of Southern Nevada Dental Faculty Practice

Practice Address: 6375 West Charleston Blvd. Suite #: A500

City: Las Vegas State: NV Zip: 89146

Telephone: 702-651-5510 Fax: 702-651-7383 Email: patientservicesdfp@csn.edu

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case # 99-526		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/7/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Vennochi

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/7/2024

Date

5/7/24

Date

Board Use Only: Date Processed: 5/28/24 Amount: $200-cc

Credentials	Practitioner Name	Speciality Details	Location	Status	Public Health	Action

Full Name :	Vennochi, John Henry , DMD
Primary Office Address :	7180 Cascade Valley Ct, Suite 240
City, State Zip :	Las Vegas, NV 89128
Office Phone :	
License Number :	2510
License Date :	03/22/1989
Status :	Active
Expiration Date :	06/30/2025
Graduated From :	Massachusetts-Tufts University School of Dental Medicine
Graduation Date :	06/01/1981

Permits :

Permit	Permit Number	Issue Date	Exp Date

Board Action / Malpractice :

Action Type	Date	Document Link
Board Action	05/26/2005	
Board Action	06/27/2008	
Board Action	06/01/2000	
Board Action	10/15/2010	

← Close detail

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STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D.M.D., Respondent.	CASE NO.: 05-1160 **STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.D.S. (Hereinafter "Respondent"), by and through his counsel, JOHN R. LUSK, ESQ., and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through Disciplinary Screening Officer, J. PAUL ANDERSON, D.M.D., D.S.O., and Board's counsel, JOHN A. HUNT, ESQ., of the law firm of RALEIGH, HUNT & McGARRY, P.C. as follows:

1. On December 13, 2002, Respondent entered into a memorandum of understanding with Zinovi Ladizhensky, a/k/a Zori Ladin, a/k/a Zori Ladizhensky, d/b/a Paradise Village Dental Center ("Zori"), wherein Zori would provide administrative/support services to Respondent.

2. On October 28, 2003, the Board notified Respondent of a verified complaint received from John Flood. On November 10, 2003, Respondent filed an answer to the complaint with the Board.

3. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.M.D., applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986); *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, finds there is substantial evidence that Respondent rendered treatment below the standard of care to John Flood in violation of NRS

JRL JHV

RALEIGH, HUNT & McGARRY, P.C.
Law Offices
112 GARCES AVE
SUITE 200
LAS VEGAS, NEVADA 89101
(702) 386-4841

631.3475(1) &(4).

4. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.S.O., under the administrative standard of proof as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), but not for any other purpose, finds there is substantial evidence Respondent, on more than one occasion, allowed Zori, to perform dental treatments beyond the scope of practice set forth in NAC 631.220 in violation of NRS 631.3475(1) & (4).

5. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.M.D., applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986); *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, finds there is substantial evidence that Respondent did not report to the Board the civil malpractice lawsuit, *John J. Flood v. Mohamad Malaki, D.D.S., John H. Vennochi, D.M.D. et al*, filed on September 21, 2004, in the Eighth Judicial District Court, Case No. A492330, in violation of NAC 631.155(5).

6. The pertinent part of the statutes and regulations cited are as follows:

NRS 631.3475 The following acts among others, constitute unprofessional conduct:

1. Malpractice;

* * *

4. More than one act by the dentist or dental hygienist constituting substandard care in the practice of dentistry or dental hygiene.

NAC 631.220

A dentist who is licensed in the state of Nevada may authorize a dental assistant in his employ and under his supervision only to do one or more of the following:

1. Expose radiographs.

JRL JHV

2. Retract a patient's cheek, tongue or other tissue during a dental operation.

3. Remove the debris which normally accumulates during or after a cleaning or operation by the dentist by using mouthwash, water, compressed air or suction.

4. Place or remove a rubber dam and accessories used for its placement.

5. Place and secure an orthodontic ligature.

6. Remove sutures.

7. Place and remove a periodontal pack.

8. Remove excess cement from cemented restorations and orthodontic appliances. A dental assistant may not use a rotary cutting instrument to remove excess cement from restorations or orthodontic appliances.

9. Administer a topical anesthetic in any form except aerosol.

10. Train and instruct persons in the techniques of oral hygiene and preventive procedures.

11. Take the following types of impressions:

(a) Those used for the preparation of diagnostic models;
(b) Those used for the preparation of counter or opposing models;
(c) Those used for the fabrication of temporary crowns or bridges; and
(d) Those used for the fabrication of temporary removable appliances, provided no missing teeth are replaced by those appliances.

12. Fabricate and place temporary crowns\ and bridges. This procedure must be checked and approved by the supervising dentist before dismissal of the patient from the office of the dentist.

13. Retract gingival tissue if the retraction cord contains no medicaments that have potential systemic side effects.

14. Remove soft plaque and stain from exposed tooth surfaces, utilizing an appropriate rotary instrument with a rubber cup or brush and a suitable polishing agent. A licensed dentist or dental hygienist shall determine that the teeth to be polished are free of calculus or other extraneous material.

15. Administer a topical fluoride.

JRL JHV

16. Apply pit and fissure sealant to the dentition for the prevention of decay. This procedure must be checked and approved by the supervising dentist before dismissal of the patient from the office of the dentist.

17. Fit orthodontic bands and prepare teeth for orthodontic bands if the bands are cemented or bonded, or both, into the patient's mouth by the dentist who authorized the dental assistant to perform this procedure.

NAC 631.155
Each licensee shall, within 30 days after the occurrence of the event, notify the Board in writing by certified mail of:

*****

5. The filing and service upon him of any claim or complaint of malpractice.

7. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates the rendered treatment to John Flood was below the standard of care in violation of NRS 631.3475(1) and (4).

8. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135. *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates that on more than one occasion Respondent allowed Zori to perform procedures beyond the permissible scope set forth in NAC 631.220 in violation of NRS 631.3475(1) and (4).

9. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates that he failed to report to the Board the filing of the civil malpractice complaint, *John J. Flood v. Mohamad Malaki, D.D.S., John H. Vennochi et al*, filed in the Eighth Judicial District Court, Case No. A492330, in

JRL JHV

violation of NRS 631.155.

10. Based upon the stipulations contained in paragraphs 7, 8 and 9, the parties have agreed to resolve the pending disciplinary action pursuant to the following terms:

a. Pursuant to NRS 631.350(h), Respondent's dental practice shall be supervised for a period of two (2) years from the adoption of this Stipulation. During the two (2) year period, Respondent shall allow either the Executive Director of the Board and/or the agent appointed by the Executive Director of the Board to inspect Respondent's records and observe the daily operation of Respondent's dental practice during normal business hours without notice to insure compliance of this Stipulation. The supervision shall include, but will not be limited to, personally observing the treatment rendered to patient(s) as well as contacting patients who have received treatment. In the event the Board's Executive Director finds there is substantial evidence Respondent has refused to either allow the copying of patient records or observation of Respondent's practice during the supervisory period, the Executive Director, shall automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada. In the event Respondent does not actively practice dentistry in the State of Nevada, the supervisory period shall be tolled for the period of inactive practice.

b. Pursuant to NRS 631.350(h), during the two (2) year supervisory period, Respondent agrees to the following conditions:

i. Patient(s) may not receive treatment(s) or be seated in an operatory unless there is a dentist licensed in the State of Nevada physically present or unless a hygienist licensed in the State of Nevada is performing hygiene treatments in compliance with NRS and NAC 631;

ii. Respondent shall obtain a written acknowledgment from present and future employees and/or independent contractors that they have received and read a copy of this Stipulation. Respondent shall maintain the written acknowledgment(s) in Respondent's office for inspection.

iii. In the event the Board's Executive Director finds there is substantial evidence Respondent has violated any of the provisions contained in either paragraph 10(b)(i) or 10(b)(ii) during the supervised period the Executive Director shall, automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada.

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c. Based upon the stipulation set forth in paragraph 8, and the anticipated continuing relationship between Respondent and Zori, Respondent agrees as long as Zori performs any services in any capacity to Respondent, Respondent agrees to the following conditions:

i. Zori, shall not at any time perform dental assisting duties as set forth in either NRS or NAC 631 while associated with Respondent or any other licensed dentist in Nevada;

ii. Zori is prohibited from being physically present at any time in the operatory(s) when patient(s) are seated in a dental chair;

iii. Zori is prohibited from participating in the negotiation of any disputes between Respondent and/or dentist or hygienist employed by Respondent regarding the treatment(s) of patient(s). Resolution of any disputes with patients must be contained in a patient's chart and sign off by Respondent; and

iv. In the event the Board's Executive Director finds there is substantial evidence Respondent has violated any of the provisions contained in either paragraph 10(c)(i) or 10(c)(ii) or 10(c)(iii), the Executive Director shall, automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate her license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada.

d. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, Respondent shall obtain a total of twenty-four (24) additional hours of supplemental education. Twelve hours (12) hours of supplemental education must be received in the area of diagnosis and treatment planning and twelve (12) hours of supplemental education must be received in the area of fixed prosthetics. All supplemental education must be completed within two (2) years of the approval of this Stipulation by the Board. The supplemental education must be submitted in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board shall notify Respondent in writing whether the requested supplemental education is approved for attendance. All costs associated with this supplemental education shall be paid by Respondent. In the event Respondent fails to complete all of the supplemental education within two (2) years, Respondent agrees his license to practice dentistry in the State of Nevada shall automatically be suspended without any further action of the Board other than the issuance of an order by the Executive Director. Upon submitting written proof of completion of the supplemental education, Respondent's license to practice dentistry in the State of Nevada will be automatically reinstated. Respondent agrees to waive any right to seek injunctive relief from any Federal or State of Nevada District Court to prevent the automatic suspension of Respondent's license to practice dentistry in the State of Nevada due to Respondent's failure to comply with Paragraph 10(d). Respondent shall also be responsible for any costs or attorney's fees incurred in the event the Board has to seek

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injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

e. Respondent agrees to reimburse the Board for costs of the investigation and to monitor this Stipulation in the amount of Seven Thousand Five Hundred Dollars ($7,500.00), pursuant to the following payment schedule:

i Prior to the adoption of this Stipulation, Respondent shall deliver the initial sum of Three Thousand Dollars ($3,000.00) to the Board. If the Board does not adopt this Stipulation the Three Thousand Dollars ($3,000.00) will be returned in full to Respondent.

ii. Thereafter, for the next twenty-four (24) months, on the first business day of each month, Respondent shall deliver to the Board's office located at 6010 S. Rainbow Blvd. Bldg. A, Suite 1, Las Vegas, Nevada, the sum of One Hundred Eighty-Seven and 50/100 Dollars ($187.50) to satisfy the remaining balance due of Four Thousand Five Hundred Dollars ($4,500.00) for costs of this investigation and to monitor this Stipulation.

f. Pursuant to NRS 631.350(1), Respondent agrees to reimburse, Mr. John Flood the amount of Ten Thousand Dollars ($10,000.00) pursuant to the following payment schedule:

i Prior to the adoption of this Stipulation, Respondent shall deliver the initial sum of One Thousand Dollars ($1,000.00) to the Board. If the Board does not adopt this Stipulation the One Thousand Dollars ($1,000.00) will be returned in full to Respondent.

ii. Thereafter, for the next twenty-four (24) months, on the first business day of each month, Respondent shall deliver to the Board's office located at 6010 S. Rainbow Blvd. Bldg. A, Suite 1, Las Vegas, Nevada, the sum of Three Hundred Seventy-Five Dollars ($375.00) to satisfy the remaining balance due of Nine Thousand Dollars ($9,000.00) to reimburse Mr. John Flood.

g. In the event Respondent fails to deliver any of the payments required pursuant to Paragraph 10(e) or 10 (f), Respondent agrees his license to practice dentistry in the State of Nevada shall automatically be suspended without any further action of the Board other than issuance of an order by the Executive Director. Failure to deliver payment would include any checks returned for insufficient funds. Respondent agrees to the payment of twenty-five dollars ($25.00) for each day Respondent fails to deliver any of the payments required by Paragraph(s) 10(e) or 10(f). Respondent may cure any default regarding the payments set forth in Paragraph 10(e) or 10(f), by delivering to the Board's Executive Director the total amount in default, plus the twenty-five dollar ($25.00) per day assessment. Upon receipt of payment in full of any amount in default, plus the twenty-five dollar ($25.00) per day assessment, the Executive Director shall without any further action of the Board reinstated Respondent's license to practice dentistry in the State of Nevada, assuming there are no other violations of any of the provisions contained in this Stipulation. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to curing any default on the amounts due and owing.

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h. In the event Respondent fails to cure any default in payment within forty-five (45) days of the default, Respondent agrees the amount may be reduced to judgment.

i. Respondent waives any right to have the amounts owed pursuant Paragraph 10(e) or 10(f) discharged in bankruptcy.

j. Respondent, pursuant to NRS 631.350(1)(j), shall retake the jurisprudence test as required by NRS 631.240(2) on the contents and interpretation of NRS 631 and the regulations of the Board. Respondent shall have ninety (90) days assuming adoption of the Stipulation to complete the re-examination. The jurisprudence examination is administered on the first Monday of each month at 10:00 a.m. and 2:00 p.m. at the Board's office. Respondent shall contact the Board to schedule a time to submit to the re-examination. In the event Respondent fails to successfully complete the re-examination within ninety (90) days of adoption of this Stipulation, Respondent agrees his license to practice dentistry in the State of Nevada shall be automatically suspended without any further action of the Board other than issuance of an order by the Executive Director. Upon successful completion of the re-examination, Respondent's license to practice dentistry in the State of Nevada will be automatically reinstated. Respondent agrees to waive any right to seek injunctive relief from any Federal or State of Nevada District Court to prevent the automatic suspension of Respondent's license to practice dentistry in the State of Nevada due to Respondent failure to comply with Paragraph 10(j). Respondent shall also be responsible for any costs or attorney's fees incurred in the event the Board has to seek injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

k. Respondent agrees a representative of the Board shall make a presentation to Respondent's staff regarding the scope of practice of dental assistants and those procedures which the staff may perform in compliance with NRS 631 and NAC 631.

CONSENT

11. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

12. Respondent is aware by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

13. Respondent expressly waives any right to challenge the Board for bias in deciding whether or not to adopt this Stipulation in the event this matter was to proceed to a full Board hearing.

14. Respondent has reviewed the Stipulation with his attorney, John R. Lusk, Esq., who has explained each and every provision contained in this Stipulation to the Respondent.

15. Respondent acknowledges he is consenting to this Stipulation voluntarily, without

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coercion or duress and in the exercise of his own free will.

16. Respondent acknowledges no other promises in reference to the provisions contained in this Stipulation have been made by any agent, employee, counsel or any person affiliated with the Nevada State Board of Dental Examiners.

17. Respondent acknowledges the provisions in this Stipulation contain the entire agreement between Respondent and the Board and the provisions of this Stipulation can only be modified, in writing, with Board approval.

18. Respondent agrees in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

19. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation and, if the Stipulation is rejected by the Board, further disciplinary action may be implemented. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this Stipulation, such adoption shall be considered a final disposition of a contested case. Respondent acknowledges and agrees of this Stipulation shall be made available to the public inspection and copying. Respondent acknowledges and agrees copies of this Stipulation may be disseminated by the Board to the public, or any licensing board or any agency which is investigating Respondent, including but not limited to any law enforcement agency. Respondent agrees and acknowledges this Stipulation shall be reported to the National Practitioners Data Bank.

DATED this 17th day of March, 2005.

JOHN H. VENNOCHI, D.M.D.
Respondent

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SUBSCRIBED and SWORN to before me this 17th day of March, 2005.

NOTARY PUBLIC

GENELLE L. PRESCOTT
Notary Public State of Nevada
No. 94-1450-1
My appt. exp. Dec. 16, 2006

APPROVED AS TO FORM & CONTENT

JOHN A. HUNT, ESQUIRE
Raleigh, Hunt & McGarry, P.C.
Board Counsel

APPROVED AS TO FORM & CONTENT

J. PAUL ANDERSON, D.M.D., D.S.O.
Disciplinary Screening Office/Informal
Hearing Officer

APPROVED AS TO FORM & CONTENT

JOHN R. LUSK, ESQ.
Attorney for Respondent

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 6 day of June, 2005.

NEVADA STATE BOARD OF DENTAL EXAMINERS

TONY GUILLEN, D.D.S.
President

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BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

NOTICE OF ENTRY OF FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631 & CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)

TO: Respondent, JOHN VENNOCHI, DMD; and

TO: JOHN R. LUSK, ESQ., Respondent's attorney:

YOU, AND EACH OF YOU WILL PLEASE TAKE NOTICE that the Findings and Recommendations of the Informal Hearing Held Pursuant to NRS 631 and NAC 631 & Consent of John Vennochi, DMD To The Findings and Recommendations Pursuant to N.R.S. 631.363(5) was entered in the above-entitled matter on June 27, 2008, a copy of which is attached hereto.

RESPECTFULLY SUBMITTED this 21 day of July, 2008.

FOX ROTHSCHILD, LLP

John A. Hunt, Esq.
Nevada Bar No. 1888
3800 Howard Hughes Pkwy., Suite 500
Las Vegas, Nevada
Attorneys for Complainant

: Rothschild LLP
) Howard Hughes Parkway
e 500
Vegas, Nevada 89169

CERTIFICATE OF MAILING

I HEREBY CERTIFY that on the 21 day of July, 2008, I served a true copy of the above and foregoing **NOTICE OF ENTRY OF FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631 & CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)** by causing same to be deposited in the United States Mail, at Las Vegas, Nevada, in a sealed envelope, first class postage thereon fully prepaid, addressed as follows:

John R. Lusk, Esq.
517 South Third Street
Las Vegas, NV 89101
Attorney for Respondent

Employee of Fox Rothschild, LLP

BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631
&
CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)

I.

INTRODUCTION

1. On December 10, 2007, an informal hearing was held in Las Vegas, Nevada, regarding alleged violations of chapter 631 of the Nevada Revised Statutes ("NRS") and chapter 631 of the Nevada Administrative Code ("NAC") by licensee, JOHN VENNOCHI, DMD. The informal hearing was held pursuant to NRS § 631.363 and NAC §§ 631.250 and 631.255.

2. In attendance at the informal hearing was J. GORDON KINARD, D.D.S., Informal Hearing Officer assigned to this matter; Debra Shaffer, Deputy Executive Director of the Board and Board attorney, JOHN A. HUNT, ESQ., licensee, JOHN VENNOCHI, D.M.D. (hereinafter referred to as "Respondent" or "Dr. Vennochi"), and his attorney, JOHN R. LUSK, ESQ.

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3. Discussed at length during the informal hearing was the following matters:

A. Whether Respondent had administered, dispensed or prescribed any controlled substance or any dangerous drugs drug as defined in Chapter 454 of NRS to Patients "A", "B" , "C", "D", "E" or "F" that were not required for a dental treatment in violation of NRS 631.3475(5).

B. Whether Respondent issued any controlled substances on more than one occasion as defined in Chapter 454 to Patients "A", "B" , "C", "D", "E" or "F" while Respondent did not possess a valid license to prescribe control substances from the Nevada State Board Pharmacy in violation of NRS 631.3485(2) or NAC 631.230(1)(d) and/or NRS 631.349.

C. Whether Respondent failed to provide the records for Patients "A", "B" , "C", "D", "E" or "F" in violation of NRS 631.3485(4) or NAC 631.230(1)(q) and/or NAC 631.240(1)(c).

D. Whether Respondent's record keeping for Patients "A", "B" , "C", "D", "E" or "F", was in violation of NRS 631.3475(4) and/or NAC 631.230(1)(c).

E. Whether Respondent issued prescriptions for controlled substances for Patients "A", "B" , "C", "D", "E" or "F" in such excessive amounts to constitute a departure from prevailing standards of acceptable dental practice in violation of NAC 631.230(1)(b).

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F. Pursuant to NRS 629.061(4) the identity of Patients "A", "B" , "C", "D", "E" or "F" must remain anonymous. Respondent has been provided with the identity of Patients "A", "B" , "C", "D", "E" and "F" and each were discussed during the course of the Informal Hearing held on December 10, 2007.

II.

FINDINGS OF FACT

4. Based upon the investigation conducted to date; the information presently available for review, including Dr. Vennochi's response to questions posed during the informal hearing, Dr. J. Gordon Kinard, as the Informal Hearing Officer assigned, issues for following findings of fact:

A. According to the testimony of Respondent, prior to 1993 a patient of Respondent acquired Respondent's prescription pad and issued numerous unauthorized prescriptions. As a result the Massachusetts Dental Board conducted an investigation. On March 27, 1997 an Order to Show Cause was made by the Massachusetts Dental Board charging that Respondent had issued eleven (11) prescriptions for controlled substances to different patients which were not issued for a legitimate medical purposed in the usual course of Respondent's dental practice and Respondent's conduct in issuing the eleven (11) prescriptions did not meet the generally accepted standards of the practice of dentistry. As a result of the Order to Show Cause, Respondent entered into a Consent Agreement with the Massachusetts Dental Board dated September 3, 1997. Pursuant to the terms of the Consent Agreement Respondent, without admitting guilt, consented to the findings that sufficient facts existed from which the Board

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could conclude that regarding four of the eleven prescriptions were not issued for a legitimate medical purposed in the usual course of Respondent's dental practice and did not meet the generally accepted standards of the practice of dentistry in violation of G. .L. c . 94C, s. 19(a) and G. L. C. 112, s. 61. As a result Respondent was placed on probation for a minimum of two (2) years and Respondent was required to attend drug and alcohol counseling and submit to random drug testing.

B. On June 1, 2000, Respondent entered into a Stipulation with the Board consenting and agreeing to the following pertinent terms and conditions:

(1). Respondent did not contest and consented to a finding that Respondent violated NRS 631.3475(5), which states the following acts, among other, constitute unprofessional conduct:

". . . .5. Administering, dispensing or prescribing any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patient;. . . ."

(2). Respondent did not contest and consented to a finding that Respondent violated NAC 631.230(1)(b) which states the following acts, among other, constitute unprofessional conduct:

" . . . .(b) Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from prevailing standards of acceptable dental practice.. . . ."

(3). Respondent did not contest and consented to a finding that his charting and record keeping practices violated NRS 631.075, NRS 631.095, NRS 631.3475(4), and NAC 631.230(1)(c).

(4). Respondent did not contest and consented to a finding that Respondent tested positive for illegal drugs on July 6, 1999.

(5). Respondent agreed to suspension of his license to practice dentistry in the

State of Nevada for a period of six (6) months, effective from the date the Board approves this Stipulated Settlement.

(6). Respondent agreed to attend sixteen (16) hours of supplemental education in the field of pharmacology and pain management prior to completion of the six (6) month suspension period.. . . .

(7). Respondent agreed to submit to random sampling of urine and/or bodily fluids for a period of five (5) years when so ordered by the Executive Director of the Board. In addition to the random drug tests which may be ordered during the five (5) year period, for one (1) year subsequent to the Board's adoption of this Stipulated Settlement, Respondent agreed to submit to urinalysis testing on the first day of the each month at Associated Pathology Laboratories (APL). . . .

. . . . .

(8). Respondent agreed to surrender his license No. CS7855 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. . . . .

(9). Respondent agrees to surrender his Registration Certificate No. BV3942477 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. . . . .

(10). Respondent's agreed his practice would be supervised for a period of five (5) years to review patient records to assure Respondent's prescription practice are in compliance with NRS 631 and NAC 631. . . . . Respondent was required to maintain, for a period of five (5) years, a list of any prescriptions issued to any of Respondent's patients by any other licensed dentist in the State of Nevada. The list of prescriptions to Respondent's patients written by any other license dentist in the State of Nevada had to include patient's name, date of issuance, licensed dentist who issued the prescription, units and amount of prescription narcotics issued.. . . . .

(11). Respondent agreed to a fine in the amount of $2,000.00 for violations of NRS 631 and NAC 631, . . .

. . . .

(12). Respondent agreed to reimburse the Board the sum of $9500.00 for the cost of this investigation and subsequent monitoring. . . . .

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Respondent successfully completed the terms and conditions of the Stipulation entered with the Board on May 31, 2005.

C. On June 13, 2005, Respondent entered into a Second Stipulation with the Board consenting and agreeing to the following pertinent terms and conditions:

(1). Respondent agreed his dental practice would be supervised for a period of two (2) years from the adoption of this Stipulation. . . . .

(2). During the two (2) year supervisory period, Respondent agreed to the following conditions:

i. Patient(s) may not receive treatment(s) or be seated in an operatory unless there is a dentist licensed in the State of Nevada physically present or unless a hygienist licensed in the State of Nevada is performing hygiene treatments in compliance with NRS and NAC 631;

ii. Respondent shall obtain a written acknowledgment from present and future employees and/or independent contractors that they have received and read a copy of this Stipulation. Respondent shall maintain the written acknowledgment(s) in Respondent's office for inspection.

. . .

(3). Based upon the anticipated continuing relationship between Respondent and Zori, Respondent agreed as long as Zori performs any services in any capacity to Respondent, Respondent agreed to the following conditions:

i. Zori, shall not at any time perform dental assisting duties as set forth in either NRS or NAC 631 while associated with Respondent or any other licensed dentist in Nevada;

ii. Zori is prohibited from being physically present at any time in the operatory(s) when patient(s) are seated in a dental chair;

iii. Zori is prohibited from participating in the negotiation of any disputes between Respondent and/or dentist or hygienist employed by Respondent regarding the treatment(s) of patient(s). Resolution of any disputes with patients must be contained in a patient's chart and sign off by Respondent; and

. . . .

(4). Respondent agreed to obtain a total of twenty-four (24) additional hours

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of supplemental education. Twelve hours (12) hours of supplemental education must be received in the area of diagnosis and treatment planning and twelve (12) hours of supplemental education must be received in the area of fixed prosthetics. . . . .

(5). Respondent agreed to reimburse the Board for costs of the investigation and to monitor this Stipulation in the amount of Seven Thousand Five Hundred Dollars ($7,500.00) . . . .

(6). Respondent agreed to reimburse, Mr. John Flood the amount of Ten Thousand Dollars ($10,000.00) . . . .

. . . .

(7). Respondent, agreed to retake the jurisprudence test as required by NRS 631.240(2) on the contents and interpretation of NRS 631 and the regulations of the Board.. . . .

(8). Respondent agreed a representative of the Board would make a presentation to Respondent's staff regarding the scope of practice of dental assistants and those procedures which the staff may perform in compliance with NRS 631 and NAC 631.

Respondent successfully completed the terms and conditions of the Stipulation entered with the Board on June 12, 2007.

D. Respondent failed to renew his controlled substances registration (CS07588) with the Nevada State Board of Pharmacy prior to the renewal dead line of October 31, 2006.

E. On May 30, 2007, Respondent attempted to reinstate his controlled substances registration (CS07588) by submitting a license renewal application with the Nevada State Board of Pharmacy . Upon submission of the application of renewal from May 30, 2007 until October 17. 2007, Respondent did not receive any correspondence from the Nevada State Board of Pharmacy reinstating Respondent's controlled substances registration (CS07588). During the

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period of October 31, 2006 until submission of his application for renewal on May 30, 2007, Respondent issued a number of prescriptions for controlled substances while not possessing a valid license to issued controlled substances in the State of Nevada. From May 30, 2007 when Respondent submitted his application to reinstate his controlled substance registration (CS07588) through October 17, 2007, Respondent issued a number of prescriptions for controlled substances while not possessing a valid license to issued controlled substances in the State of Nevada.

F. On June 21, 2007 at a properly noticed meeting the Board approved and authorized an investigation whether Respondent had possibly violated NRS 631.3475(5) regarding patients "A" and "B". On July 17, 2007, Respondent was given notice of the authorized investigation complaint. On July 30, 2007, Respondent submitted answer to the authorized investigation complaint which included but was not limited to Respondents contention that Patient "A" has forged Respondent signature on the prescriptions in question for Patients "A", "B" and "C". On October 16, 2007, Respondent was given supplemental information and documentation obtained by the Board during the course of the investigation regarding Patients "A" and "B". On October 24, 2007, Respondent submitted a supplemental response to the authorized investigation complaint stating the prescriptions issued to Patients "A", "B" , and "C", on October 17, 2006, December 4, 2006, December 11, 2006, January 12, 2007, February 26, 2007 and April 17, 2007 were forgeries.

G. On October 17, 2007 the Board received a copy of correspondence from Louis Ling, General Counsel for the Nevada State Board of Pharmacy to Respondent regarding Respondent's status with the Pharmacy Board. General Counsel Louis Ling stated the

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following:

(1). Respondent did not timely renew his controlled substances registration (CS07588) by October 31, 2006. Therefore Respondent's registration lapsed as of November 1, 2006 which meant Respondent could not lawfully prescribe, possess, administer or dispense, controlled substances in Nevada effective November 1, 2006.

(2). On May 30, 2007, Respondent submitted a late renewal application along with a check. The check was not deposited by the Pharmacy Board. That Respondent did not receive any indication from the Pharmacy Board that Respondent's registration was renewed.

(3). Respondent's renewal was not processed and would not be possessed until the pending investigation with the Nevada State Board of Dental Examiners was resolved

H. On October 23, 2007, Respondent was served with a Notice of Inspection of Patient Records for Patients "D", "E" and "F".

I. On October 24, 2007, Respondent sent correspondence to the Culinary Free Pharmacy indicating a generic Rx pad had been stolen from his practice in October 2006. Subsequently there had been numerous Rx written for Lortab 10. Those Rx's were all made out to Patients "A", "B" , and "C", and that all were forgeries. Respondent further instructed the Culinary Free Pharmacy not to fill any prescriptions written on Paradise Village Dental Center Rx paper and to contact Respondent immediately.

J. On October 31, 2007, Respondent was served with the Notice of Informal Hearing and a Subpoena Duces Tecum regarding Patients "A", "B", "D", "E" and "F".

K. On December 10, 2007 an Informal Hearing was held at Respondent's attorney's office located at 517 South Third Street , Las Vegas, Nevada. Those individuals present were Respondent, his attorney John R. Lusk, Esq., Disciplinary Screening Officer James G. Kinard,

Debra A. Shaffer, Board Deputy Executive Director and Board Counsel John A. Hunt, Esq.

L. The Massachusetts Consent Order dated September 3, 1997; the Stipulation with the Board date June 1, 2000; and the present authorized investigation complaint dated July 17, 2007; all involved whether Respondent issued of controlled substances that were either not related to dental treatments or involved. The Massachusetts Consent Order and the present authorized complaint both involve the issuance of forged prescription using of Respondent's prescription pads.

M. At the Informal Hearing held on December 10, 2007, Respondent gave the following testimony:

i. Respondent did not have any records for Patients "A". "B" or "C" related to the prescriptions issued and discussed to these patients. Respondent believes these prescriptions to be forgeries.

ii. Respondent has been aware since 1998 he could do a self profile with the Nevada State Board of Pharmacy, but Respondent has never done a self profile.

iii. Respondent acknowledges since November 1, 2006, Respondent has issued on more than one occasion prescriptions for controlled substances while not possessing a valid license with the Nevada State Board of Pharmacy.

iv. Respondent did not report on his attempted license renewal of May 30, 2007 the Consent Order with the Massachusetts Dental Board or the Second Stipulation entered into with the Nevada State Board of Dental Examiners to the Nevada State Pharmacy Board .

v. Since receiving the authorized investigation complaint of July 17, 2007, Respondent never reported to the Nevada State Board of Pharmacy, but did report in writing to the Disciplinary Screening Officer on July 30, 2007, Respondent's contention that ~~his~~ the prescription pad at his prior practice had been stolen by Patient "A" who was also an employee of Respondent who he believes wrote other forged prescriptions to for Patient "A", "B" and "C". October 24, 2007 three months after Respondent's belief his prescription pad had be stolen by Patient "A", Respondent wrote

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to the Culinary Free Pharmacy regarding his suspicions regarding Patient "A" and not to fill any prescriptions made to Patient "A", "B" or "C" and to contact Respondent.

vi. Respondent does not have any dental records or treatment plan regarding a prescription for a controlled substance written to Patient "D" on September 22, 2007 while Respondent did not possess a valid license to issue controlled substances with the Nevada State Board of Pharmacy. It is Respondent's contention that the treatments received by Patient "D" subsequently on January 11, 14 and 22 2008 related to the prescription issued to Patient "D" on September 22, 2007.

vii. Respondent does not have any dental records or treatment plan regarding a prescription for a controlled substance written to Patient "E" on January 11, 2007 while Respondent did not possess a valid license to issue controlled substances with the Nevada State Board of Pharmacy.

viii. Respondent while he did not possess a license with the Nevada State Board of Pharmacy issued three (3) prescriptions to Patient "F" on April, 20, 2007, April 24, 2007 and April 28, 2007; each prescription was written for 20 units of Hydrocodone Bitartrate and Acetaminophen, 500 mg; 7.5 mg tablet. The April 28, 2007 prescription did not appear in the dental records of Patient "F".

II.

CONCLUSIONS OF LAW

5. Based upon the findings of facts cited above; the investigation conducted to date; the limited information presently available for review and Respondent's responses to questions posed during the informal hearing, Dr. J. Gordon Kinard, as the Informal Hearing Officer assigned, issues for following conclusions of law:

A. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence Respondent had administered,

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dispensed or prescribed controlled substances or dangerous drugs drug as defined in Chapter 454 of NRS to Patient "E" that were not required for a dental treatment in violation NRS 631.3475(5).

B. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent issued controlled substances on more than one occasion as defined in Chapter 454 to Patients "D", "E" or "F" while Respondent did not possess a valid license to prescribe control substances from the Nevada State Board Pharmacy in violation of NRS 631.3485(2) or NAC 631.230(1)(d) and/or NRS 631.349.

C. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent failed to provide the records for Patients "D", "E" or "F" in violation of NRS 631.3485(4) or NAC 631.230(1)(q) and/or NAC 631.240(1)(c).

D. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent's record keeping for Patients "D", "E" or "F", was in violation of NRS 631.3475(4) and/or NAC 631.230(1)(c).

E. It is the finding of the Informal Hearing Officer, based upon the limited

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information presently available, that there is substantial evidence that Respondent issued prescriptions for controlled substances for Patients "D", "E" or "F" in excessive amounts to constitute a departure from prevailing standards of acceptable dental practice in violation of NAC 631.230(1)(b).

III.

RECOMMENDATIONS

6. Based upon the findings of fact and conclusions of law as more fully addressed above and taking into consideration present violations are similar to the prior administrative actions taken by the Dental Board Of Massachusetts and the Nevada State Board of Dental Examiner this Informal Hearing Officer makes the following Recommendations:

A. Pursuant to N.R.S. § 631.350(b), Respondent's license to practice dentistry in the State of Nevada should be suspended for a period of four (4) months in the event Respondent consents and the Board adopts these Findings and Recommendations. TO be effective July 26, 2008 IF adopted by Board.

B. Pursuant to NRS 631.350(1)(d) s after completing the four (4) month suspension period this Informal Hearing Officer recommends Respondent be placed probation for a period of five (5) years pursuant to the following terms and conditions:

i. Respondent should surrender his license No. CS7855 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years. At the end of the five (5) year probationary period Respondent should be allowed apply to have his prescription writing privileges with the Nevada State Board of Pharmacy reinstated.

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ii. Respondent should surrender his Registration Certificate No. BV9085033 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years. In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to the D.E.A. to have his prescription privileges reinstated.

iii. The terms and conditions of the probation should be reported to the National Practitioners Data Bank. In the event Respondent does not actively practice dentistry in the State of Nevada the probationary period should be tolled for the period on inactive practice.

iv. Respondent should allow either the Executive Director of the Board and/or agent(s) appointed by the Board's Executive Director to inspect Respondent's records to ensure compliance during the probationary period. Such inspections should be performed, without notice, during normal business hours. During the probationary period Respondent may issue prescriptions for non-narcotic controlled substances pursuant to the terms set forth below. During the probationary period Respondent will prohibited from issuing any prescriptions for Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substances. In the event a patient of Respondent requires a prescription for a Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substance during the probationary period, Respondent will be allowed to authorized a dentist licensed in Nevada to issue such a prescription on his behalf. The prescribing dentist must physically examine the patient. The examination, prescription, and quantity must be entered into the patient's record by the prescribing dentist in his/her own handwriting unless Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered,. Respondent will be responsible for making sure these entries are in the patient's records. Respondent is prohibited from receiving any pre-signed prescription(s) from a dentist who is issuing a prescription on behalf of any of Respondent's patient(s). All prescriptions issued by Respondent during the probationary period for non-narcotic controlled substances must be in Respondent's handwriting and must have an original signature of Respondent. Respondent must maintain a copy of any prescriptions issued by Respondent for non-narcotic controlled substances. Such copies shall be attached to reports submitted on the first day on each month. During the probationary period Respondent should be allowed to place telephone prescriptions for ~~antibiotics~~ NON NARCOTIC CONTROLLED SUBSTANCES OR ANTIBIOTICS. CLASS II THROUGH VI All prescriptions issued by a dentist on behalf of Respondent during the probationary period for Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substances should be required to be in that dentist's own handwriting and must have an original signature of that dentist. Respondent should be required to maintain a copy of any prescriptions issued by a

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dentist on Respondent's behalf for Class II, Class IIN, Class III, Class IIIN, Class IV, or Class V controlled substances. Such copies shall be attached to reports submitted on the first day on each month. On the first day of each month during the probation period Respondent should be required to prepare a report listing the controlled substance prescriptions issued by any Nevada license dentist who has issued a prescription on Respondent's behalf. Attached to the report should be copies of any prescriptions issued by any Nevada licensed dentist was has issued a prescription on Respondent's behalf. The report should require the following information and shall be submitted to the Executive Director of the Board:

(a) patient's name;
(b) date of issuance;
(c) name of dentist who issued prescription;
(d) units and amount of controlled substance issued; and
(e) reason for issuing the controlled substance.

v. In the event the Board's Executive Director has substantial evidence to believe Respondent has failed to comply with any of the recommended provisions contained in Section III, 6B (iv) the Executive Director, should without further hearing or action by the Board, should issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

vi. Respondent should be required to physically surrender his License with the United States Department of Justice, D.E.A. to prescribe Class II, Class IIN, Class III, Class IIIN, Class IV, V and Class VI during the five (5) year probationary period. In the event the Board's Executive Director has substantial evidence to believe Respondent has either failed to physically surrender his DEA License or has prescribed any Class II, Class IIN, Class III, Class IIIN, Class IV, Vor Class VI controlled substances, the Executive Director, should without further hearing or action by the Board, issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

vii. Respondent should be required to physically surrender his License No. CS7855 with the with the Nevada State Board of Pharmacy to prescribed Class II, Class IIN, Class III, Class IIIN, Class IV, V and Class VI during the five (5) year probationary period. In the event the Board's Executive Director has substantial evidence to believe Respondent has either failed to physically surrender his Nevada State Board of Pharmacy License or has prescribed Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substance, the Executive Director should without further hearing or action by the Board, shall issue an Order of Revocation of Respondent's license to practice dentistry in the State of

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Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

viii. During the five (5) year probationary all chart entries on patients seen or treated by Respondent should be required to be in Respondent's own hand writing unless Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered. The patient records whether entry by hand or by computer must contain the following minimum information:

1. Date of the treatment;
2. A diagnosis for every treatment performed;
3. A description of the treatment performed;
4. Amount, concentration and types of medications given;

5. Each antibiotic prescription should be in triplicate, serially numbered prescription form which have been inspected and pre-approved by the Executive Director. A copy of each antibiotic prescription should be mailed to the Board on a monthly basis. Respondent should maintain one copy in the patients dental records.

6. For emergency or problem focused evaluations, Respondent must provide a statement in the patient's words of the problem, an observation of the patient's condition, a diagnosis, and a statement of the proposed treatment.

With the exception of viii(5)above in the event Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered, Respondent will be relieved of his obligation to hand write the such notations require by viii(1) and (2) and (3) and (4) and (6).

In the event the Board's Executive Director has substantial evidence to believe Respondent has failed to comply with any of the provisions contained in Section III, 6B (viii) the Executive Director, should without further hearing or action by the Board, shall issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

ix. Pursuant to NRS 631.350(1)(i), Respondent should be required to perform One Hundred (100) hours of approved community service at a dental public health facility. The One Hundred (100) hours of community service should be completed within four (4) years of commencement of the

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recommended five (5) year probationary period. Respondent should be required to receive prior written approval from the Board's Executive Director before administering the community service. To receive credit for any of the community service rendered Respondent should be required to have an individual who is responsible for the community service facility attest to the amount of time Respondent has rendered treatment In the event Respondent fails to complete the One Hundred (100) hours of community service within four (4) years of commencement of the recommended five (5) year probationary period Executive Director should without any further action of the Board shall issue an Order suspending Respondent's license to practice dentistry in the State of Nevada. Upon submitting written proof to the Executive Director that Respondent has completed the One Hundred (100) hours of community service the Executive Director should be required without any further action of the Board issue an Order reinstating Respondent's license to practice dentistry in the State of Nevada.

x. Respondent should be required to reimburse the Board for costs of the investigation including but not limited to attorneys fees in the amount of $10,000.00 in event Respondent consents to these Findings and Recommendation and the Board adopts same. Assuming Respondent consents to these Findings and Recommendation and the Board adopts same, Respondent be allowed to make equal monthly payments in the amount of $166.66. The first monthly payment should be made payable to the Board, thirty (30) days from the adoption of these consented to Findings and Recommendations by the Board.

xi. Pursuant to NRS 631.350(c) the Board should impose an appropriate fine upon Respondent in the amount of $2000.00 to be delivered to the Board ~~within ninety (90) days~~ from the adoption of these consented to Findings and Recommendations by the Board . 30 days $500, remaining balance due 5th month from adoption

xii In the event Respondent fails to deliver any of the payments required pursuant to Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) Respondent license to practice dentistry in the State of Nevada should be automatically be suspended without any further action of the Board other than issuance of an order by the Executive Director. Failure to deliver payment would include any checks returned for insufficient funds. Respondent should be required to pay twenty-five dollars ($25.00) for each day Respondent fails to deliver any of the payments required by Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) Respondent should be allowed cure any default regarding the payments set forth in Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) by delivering to the Board's Executive Director the total amount in default, plus the twenty-five dollar ($25.00) per day assessment. Upon receipt of payment in full of any amount in default, plus the twenty-five dollar ($25.00) per day assessment, the Executive Director shall without any further action of the Board reinstated Respondent's license to practice dentistry in the State of Nevada, assuming there are no other violations of any of the provisions

contained in these consented to Findings and Recommendations adopted by Board, Respondent should be required to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to curing any default on the amounts due and owing. Respondent should also be responsible for any costs or attorney's fees incurred in the event the Board has to seek injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

xii Pursuant to NRS 631.350(1)(k), within ninety (90) days adoption of these consented to Findings and Recommendations by the Board , Respondent should be required to retake the jurisprudence test as required by N.R.S. § 631.240(2) on the contents and interpretation of chapter 631 of the Nevada Revised Statutes and the regulations of the Board. The jurisprudence examination is administered on the first Monday of each month at 10:00 a.m. and 2:00 p.m. at the Board's office. Respondent should be required to contact the Board to schedule a time to submit to the re-examination. two years (2) from adoption of Findings/Recom

xiv. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, ~~during the four (4) month suspension period~~ Respondent shall be required to obtain forty (40) additional hours in supplemental education. Twenty (20) hours should be obtained in the area of -ethics, and the remaining twenty(20) hours of supplemental education should be received in the area of record keeping. F The Respondent should be required to submit in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board should be required to notify Respondent in writing whether the requested supplemental education is approved for attendance. Respondent agrees seventy (70%) per cent of the supplemental education shall be completed through attendance at live lecture. The remaining thirty (30%) per cent of the supplemental education may be completed through online/home study. Respondent should be required to pay all costs associated with this supplemental education. Respondent should not be allowed to commence the practice of dentistry until Respondent has completed the four (4) month suspension period and has submitted written proof of completion of the recommended supplemental education.

_____ this 27 day of June, 2008.
J. GORDON KINARD, D.D.S.
Informal Hearing Officer

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IV.

CONSENT TO FINDINGS AND RECOMMENDATIONS

N.R.S. § 631.363(5) states:

"5. If the person who was investigated agrees in writing to the findings and conclusions of the investigator, the Board may adopt that report as its final order and take such action as is necessary without conducting its own hearing on this matter."

7. I, JOHN VENNOCHI, DMD, hereby acknowledge that I have read N.R.S. § 631.363 (5). I am aware that if I decide not to consent to the Findings and Recommendations of the Informal Hearing Officer, a formal complaint may be filed against me. In the event a formal complaint is filed, I am aware I have the right to a full disciplinary hearing before the Nevada State Board of Dental Examiners.

8. I have read all of the Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS, and upon advice of my counsel, I consent to all of the Informal Hearing Officer's Findings and Recommendations.

9. I have reviewed the Findings and Recommendations of Informal Hearing Officer with my attorney, John R. Lusk, Esquire, who has explained each and every provision contained in all of the Informal Hearing Officer's Findings and Recommendations.

10. I further agree this consent in no way prohibits the Nevada State Board of Dental Examiners from using the findings, recommendations and information obtained from this investigation in future disciplinary actions.

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11. I further acknowledge that I am consenting to the Findings and Recommendations of the Informal Hearing Officer voluntarily, without coercion or duress, and in the exercise of my own free will.

12. I am aware by consenting to the Findings and Recommendations, I am admitting to all of the Findings and Recommendations as stated by the Informal Hearing Officer.

13. I am aware by consenting to the Findings and Recommendations, I am waiving all rights to seek judicial review or otherwise to challenge or contest the validity of the Findings and Recommendations contained herein.

14. I am aware that the Nevada State Board of Dental Examiners may choose not to adopt my consent to the Findings and Recommendations of the Informal Hearing Officer. The Findings and Recommendations and consent will be presented to the Board for ratification at its next properly noticed meeting. If the Board ratifies the Findings, Recommendations and Consent, such ratification will be considered a final disposition of a contested case and shall become a public record. Further copies of the ratified Findings and Recommendations shall be provided/reported to the public, appropriate agencies/entities, including but not necessarily limited to, the National Practitioners Data Bank.

15. I hereby specifically recognize, acknowledge and agree that failure on my part to fully

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satisfy all of the terms and conditions of the Findings and Recommendations of the Informal Hearing Officer, shall constitute unprofessional conduct; I further agree in the event I fail to satisfy all of the Findings and Recommendations of the Informal Hearing Officer, the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS.

_____ this 27th day of June, 2008.
JOHN VENNOCHI, DMD

APPROVED AS TO FORM AND CONTENT

_____ this 27th day of June, 2008.
JOHN R. LUSK, ESQ.
Respondent's attorney

V.

ACTION BY THE BOARD

The foregoing Findings and Recommendations and Consent thereto was (circle the appropriate action):

X Approved

Disapproved

by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 27th day of JUNE, 2008.

NEVADA STATE BOARD OF DENTAL EXAMINERS

_____
WILLIAM G. PAPPAS, President

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STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D. M. D., Respondent.	Case No. 00-526 **STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.M.D. (hereinafter "Respondent"), and his counsel, JOHN R. LUSK, ESQ. and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through its counsel JOHN A. HUNT, ESQ., of the law firm RALEIGH, HUNT & McGARRY, P.C. as follows:

1. On March 9, 1998, the Nevada State Board of Dental Examiners notified Respondent of a verified complaint received from patient Barbara Fuchs regarding the care and treatment received by Barbara Fuchs.

2. On April 8, 1998, the Respondent filed an answer to the complaint.

3. On March 30, 1998, pursuant to a properly noticed meeting, the Board authorized an investigation of Respondent regarding his failure to report a consent decree which was entered into with the Dental Board of the State of Massachusetts, pursuant to NAC 631.155(3).

4. On May 5, 1999, Dr. Susan Jancar, the Disciplinary Screening Officer/Informal Hearing Officer assigned, notified Respondent that an Informal Hearing would be held on June 7, 1999 to discuss the care and treatment of patient Barbara Fuchs and Respondent's license renewal application.

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5. On June 7, 1999, an Informal Hearing was held to discuss the items contained in the Notice of Informal Hearing. During the course of the Informal Hearing, pursuant to NAC 631.250, a preliminary discussion was had regarding Respondent's prescription practices as identified by the Nevada State Board of Pharmacy. Thereafter, the Informal Hearing was re-noticed for April 7, 2000.

6. On June 10, 1999, the Nevada State Board of Dental Examiners received an updated prescription profile from Keith McDonald, Executive Secretary of the Nevada State Board of Pharmacy, regarding the prescription practices of Respondent.

7. Subsequent to receiving the prescription profile from the Nevada State Board of Pharmacy, the Disciplinary Screening Officer/Informal Hearing Officer subpoenaed patient records for those individuals identified on the prescription profile from the Respondent and previous employers of Respondent.

8. Thereafter, Respondent's attorney, John Lusk, Esq., and the Board's attorney, John A. Hunt, Esq., entered into negotiations in order to protect the citizens of the State of Nevada and Respondent's due process rights. As a result of these negotiations a Stipulation was submitted and adopted by the Board on July 6, 1999 wherein Respondent voluntarily agreed not to prescribe any controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V until such time as a written agreement was entered into between the Respondent and the Board allowing Respondent to resume his privilege to prescribed controlled substances.

9. Subsequent to entering into the Stipulation with the Board, Disciplinary Screening Officer/Informal Hearing Officer, Dr. Susan Jancar, continued her investigation and reviewed the subpoena documents of patients identified on the prescription profile submitted by the Nevada State Board of Pharmacy. Respondent was notified of the intention of the Disciplinary Screening Officer/Informal Hearing Officer to renotice the informal hearing and/or file a formal complaint with

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the Nevada State Board of Dental Examiners. As a result of further negotiations, the parties have agreed to resolve the pending matters pursuant to the following consents and conditions:

a. Respondent does not contest and consents to a finding that Respondent violated NRS 631.3475(5), which states the following acts, among other, constitute unprofessional conduct:

> "....
> 5. Administering, dispensing or prescribing any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patient;
>
> ...."

b. Respondent does not contest and consents to a finding that Respondent violated NAC 631.230(1)(b) which states the following acts, among other, constitute unprofessional conduct:

> "....
>
> (b) Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from prevailing standards of acceptable dental practice.
>
> ...."

c. Respondent does not contest and consents to a finding that his charting and record keeping practices violated NRS 631.075, NRS 631.095, NRS 631.3475(4), and NAC 631.230(1)(c).

d. Respondent does not contest and consents to a finding that Respondent testing positive for illegal drugs on July 6, 1999.

10. In light of Respondent's consent to a finding of violations of the provisions of NRS Chapter 631 and NAC Chapter 631, pursuant to NRS 631.350(1)(b), Respondent agrees to suspension of his license to practice dentistry in the State of Nevada for a period of six (6) months, effective from the date the Board approves this Stipulated Settlement. Respondent shall physically deliver his license to the Board's Executive Director, located at 2295-B Renaissance Drive, Las Vegas, Nevada 89119, upon approval of the Stipulation by the Board. Provided Respondent is in

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compliance with the conditions specified herein, the Executive Director shall return Respondent's license to him on the day that represents six (6) months from the date the Board approves this Stipulation.

11. In addition to complying with the six (6) month suspension agreed upon in Paragraph 10, Respondent also agrees to abide by the following conditions:

a. In addition to complying with the continuing education requirements of NAC 631.173, pursuant to NRS 631.350(k), Respondent agrees to attend sixteen (16) hours of supplemental education in the field of pharmacology and pain management prior to completion of the six (6) month suspensionary period. The additional sixteen (16) hours must receive the approval of the Board's Executive Director prior to attendance. All costs relating to continuing education will be borne by the Respondent.

b. Pursuant to NRS 631.350(g), Respondent agrees to submit to random sampling of urine and/or bodily fluids for a period of five (5) years when so ordered by the Executive Director of the Board. In addition to the random drug tests which may be ordered during the five (5) year period, for one (1) year subsequent to the Board's adoption of this Stipulated Settlement, Respondent will submit to urinalysis testing on the first day of the each month at Associated Pathology Laboratories (APL). Should the first day of the month fall on a Saturday or Sunday, Respondent will submit the monthly sample on the first business day of the month. Any test or analysis of bodily fluids taken shall be conducted in such a manner that the testing agency shall preserve enough of the sample to allow for subsequent independent confirmatory tests. The results of any tests or analysis of bodily fluids shall be reported to the Board. Respondent shall be responsible for all costs incurred for the analysis of urine and/or bodily fluids.

c. In the event any test or analysis of bodily fluids taken from Respondent, pursuant to the terms of this Stipulation, is positive, indicating the presence of controlled substances (not pursuant to a valid prescription), Respondent will be notified and allowed to arrange for a subsequent independent confirmatory test. Should the Respondent test positive, Respondent shall voluntarily cease practicing dentistry in the State of Nevada until such time as a full Board hearing is held to evaluate the positive findings and subsequent independent confirmatory tests.

d. Should Respondent fail to present himself for random drug testing, when directed by the Executive Director of the Board, within twenty-four (24) hours of said direction by the Executive Director, Respondent's license to practice dentistry in the State of Nevada will be revoked indefinitely

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without any other action by the Board other than the entry of an appropriate Order of Revocation.

e. Respondent authorizes reports generated by the urinalysis and/or bodily fluids testing, and any substance abuse evaluation reports, and any status reports rendered by individuals treating Respondent to be furnished to the Executive Director of the Board. All reports submitted to the Executive Director of the Board shall remain confidential and for use by the Board's Executive Director only. In the event of a violation in the form of a confirmed, positive test result, all reports previously submitted to the Executive Director of the Board will be available for use by the Board in connection with any subsequent disciplinary action of the Board.

f. Respondent shall notify, in writing, each of his active patients that he will not be practicing dentistry for six (6) months subsequent to the Board's adoption of this Stipulation and will inform his patients that their records will be made available so they can procure alternate dental services, if they so desire.

g. Due to Respondent's consent to a finding of violations of NRS 631 and NAC 631 contained in Paragraph 9, Respondent agrees to surrender his license No. CS7588 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999 . In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to have his prescription writing privileges with the Nevada State Board of Pharmacy reinstated.

h. Due to Respondent's consent to a finding of violations of NRS 631 and NAC 631 contained in Paragraph 9, Respondent agrees to surrender his Registration Certificate No. BV3942477 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to the D.E.A. to have his prescription privileges reinstated.

i. Pursuant to NRS 631.350(h), Respondent's practice shall be supervised for a period of five (5) years to review patient records to assure Respondent's prescription practice are in compliance with NRS 631 and NAC 631. During the five (5) years of supervision, Respondent shall allow either the Informal Hearing Officer and/or the Executive Director of the

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Board and/or an agent appointed by the Board to inspect Respondent's records to assure compliance with this Stipulated Agreement. Such inspection shall be performed, without notice, during normal business hours. Respondent shall maintain, for a period of five (5) years, a list of any prescriptions issued to any of Respondent's patients by any other licensed dentist in the State of Nevada. The list of prescriptions to Respondent's patients written by any other license dentist in the State of Nevada shall include patient's name, date of issuance, licensed dentist who issued the prescription, units and amount of prescription narcotics issued. Respondent's failure to accurately maintain the list of prescriptions issued to his patients by any other licensed dentist in the State of Nevada shall be deem unprofessional conduct and in violation of this Stipulation and shall be considered by the Board in determining whether or not to revoke Respondent's license to practice dentistry in the State of Nevada.

j. Pursuant to NRS 631.350(c), Respondent agrees to be fined in the amount of $2,000.00 for violations of NRS 631 and NAC 631, as cited above.

k. Respondent agrees, until such time as the fine of $2,000.00 is paid, Respondent shall not practice dentistry in the State of Nevada until such time as the fine is paid in full. Respondent further agrees, in the event the Board has to initiate any legal proceedings to enforce the fine or in the event the Board has to seek injunctive relief if Respondent fails to voluntarily cease practicing dentistry in the State of Nevada, Respondent shall be responsible for legal fees and costs incurred by the Board in any such proceedings.

l. Upon approval of this Stipulation by the Board, Respondent agrees to pay the Board the sum of $9500.00 to reimburse the Board for the cost of this investigation and subsequent monitoring to enforce this Stipulation. Respondent shall pay the reimburse amount pursuant to the following schedule:

i. Upon approval of this Stipulation by the Board, Respondent shall pay the Board the sum of $1,583.35;
ii. Nine (9) months from date of the first payment, Respondent shall pay the Board the sum of $1,583.33;
iii. Six (6) months from date of the second payment, Respondent shall pay the Board the sum of $1,583.33;
iv. Six (6) months from date of the third payment, Respondent shall pay the Board the sum of $1,583.33;
v. Six (6) months from date of the fourth payment, Respondent shall pay the Board the sum of $1,583.33;
vi. Six (6) months from date of the fifth payment, Respondent shall pay the Board the sum of $1,583.33.

In the event Respondent fails to reimburse the Board for the cost of the

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investigation pursuant to the schedule cited above, Respondent shall cease practicing dentistry in the State of Nevada until such time as the payment schedule is brought current. Respondent further agrees, in the event the Board has to initiate any legal proceedings to enforce the payment schedule identified above or to seek injunctive relief if Respondent fails to voluntarily cease practicing dentistry in the State of Nevada until such time as the payments are made current, Respondent shall be responsible for legal fees and costs incurred by the Board in any such proceedings.

CONSENT

12. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

13. Respondent is aware by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

14. Respondent expressly waives any right to challenge the Board for bias in deciding whether or not to adopt this Stipulation in the event this matter was to proceed to a full Board hearing.

15. Respondent has reviewed the Stipulation with his attorney, John R. Lusk, Esq., who has explained each and every provision contained in this Stipulation to the Respondent.

16. Respondent acknowledges he is consenting to this Stipulation voluntarily, without coercion or duress and in the exercise of his own free will.

17. Respondent agrees in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

18. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation and, if the Stipulation is rejected by the Board, further disciplinary action may be implemented. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this

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Stipulation, such adoption shall be considered a final disposition of a contested case.

DATED this 14th day of MARCH, 2000.

JOHN H. VENNOCHI, D. M. D.
Respondent

SUBSCRIBED and SWORN to before me this 14th day of March, 2000.

DEBRA K. CAROSELLI
Notary Public - Nevada
No. 93-0213-1
My appt. exp. Oct. 27, 2001

NOTARY PUBLIC in and for said County and State

APPROVED AS TO FORM & CONTENT

JOHN A. HUNT, ESQUIRE
Complainant's attorney

APPROVED AS TO FORM & CONTENT

SUSAN S. JANCAR, D.D.S.
Disciplinary Screening Office/Informal Hearing Officer

APPROVED AS TO FORM & CONTENT

JOHN R. LUSK, ESQUIRE
Attorney for Respondent

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 1st day of JUNE, 2000.

NEVADA STATE BOARD OF DENTAL EXAMINERS

A. TED TWESME, D.D.S.
President

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Case No. 99-526

STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D. M. D., Respondent.	**STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.M.D. (hereinafter "Respondent"), and his counsel, JOHN R. LUSK, ESQ. and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through its counsel JOHN A. HUNT, ESQ., of the law firm of RALEIGH, HUNT & McGARRY, P.C. as follows:

1. Currently the Board is conducting an investigating into the dental practice of Respondent.

2. On June 7, 1999 an Informal Hearing was held regarding the dental practice of the Respondent.

3. On June 10, 1999, the Nevada State Board of Dental Examiners received a

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prescription inquiry from Keith W. McDonald, Executive Secretary of the Nevada State Board of Pharmacy regarding the prescription practices of Respondent.

4. At this time, without admitting to the patients or the number of times, Respondent hereby admits there is probable cause to believe Respondent has violated NRS 631.3475(5), which states the following acts, among others, constitute unprofessional conduct;

> "5. Administering, dispensing or prescribing of any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patients; ...."

5. At this time, without admitting to the patients or the number of times, Respondent admits there is probable cause to believe Respondent has violated NAC 631:230(b) which states the following acts, among others, constitutes unprofessional conduct;

> "(b) Writing prescriptions for controlled substances in an excessive amount as to constitute a departure from the prevailing standards of acceptable dentistry practice."

6. At this time, without admitting to patients or the number of times, Respondent admits there is probable cause to believe Respondent has violated NAC 631.230(1)(d) which states the following acts, among others, constitute unprofessional conduct.

> "(1)(d) The acquisition of any controlled substances from any pharmacy or other sources, by misrepresentation, fraud, deception or subterfuge."

7. Based upon the information contained in Paragraphs 1 through 6 above, Respondent hereby voluntarily agrees he will not prescribe any controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V until such time as a written agreement is entered into between the Respondent and the Board allowing Respondent to resume his privilege to prescribed controlled substances.

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8. In the event Respondent prescribes any controlled substances as defined in V prior to the Board reinstating Respondent privilege to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V, Respondent hereby stipulates and agrees the Board shall revoke Respondent's license to practice dentistry in the State of Nevada without any further action by the Board, other than appropriate order of revocation executed by the Board's Executive Director.

9. Respondent agrees, until such time as the Board completes its present investigation, Respondent's practice shall be monitored to assure Respondent does not issue any prescriptions for controlled substances, as defined in Class II, Class II-N, Class III, Class III-N, Class IV and Class V. Until the Board's present investigation is completed, Respondent shall allow either the Informal Hearing Officer, assigned to this matter and/or the Executive Director of the Board and/or any agent appointed by the Board, to inspect Respondent's office and records to insure compliance with this stipulation. Such inspection shall be performed, without notice, during normal business hours. Respondent further agrees, pursuant to the Consent Order entered into with the Commonwealth of Massachusetts, paragraphs 4B & C, Respondent shall forward to the Board's Executive Director copies of all random and supervised urine screening tests. Respondent shall also forward copies of all quarterly therapists' reports, submitted to the Commonwealth of Massachusetts.

10. Upon approval of this Stipulation by the Board, Respondent agrees to pay the Board the sum of $1,000 to reimburse the Board for the preparation of this stipulation.

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(702-386-4842

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CONSENT

11. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

12. Respondent is aware that by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

13. Respondent expressly waives any right to challenge the Board for bias should the Board reject this Stipulation and this matter proceed to a full Board hearing.

14. Respondent has reviewed every provision of this Stipulation with his attorney, JOHN R. LUSK, ESQ. and has been advised of the ramifications of each provision of the Stipulation.

15. Respondent acknowledges that he is consenting to this Stipulation voluntarily, without coercion or duress and in the exercise of his own free will.

16. Respondent agrees that in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

17. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this

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(702-366-4842

Stipulation, such adoption shall be considered a final disposition of a contested case.

DATED this 6th day of July, 1999.

SUSAN S. JANCAR, D.D.S.
Disciplinary Screening Officer/Informal Hearing Officer

JOHN A. HUNT, ESQUIRE
Attorney for Complainant

JOHN H. VENNOCHI, D.M.D.
Respondent

JOHN R. LUSK, ESQUIRE
Attorney for Respondent

STATE OF NEVADA)
) ss
COUNTY OF CLARK)

ACKNOWLEDGMENT

On this 6th day of July, 1999, personally appeared before me, a Notary Public in and for said County and State, JOHN H. VENNOCHI, D.M.D. known to me to be the person described in and who executed the foregoing instrument, who acknowledged to me that he executed the same freely and voluntarily.

DEBRA K. CAROSELLI
Notary Public - Nevada
No. 93-0213-1
My Appt. exp. Oct. 27, 2001

NOTARY PUBLIC in and for said County and State

JRL

JHV

Law Offices
RALEIGH, HUNT & McGARRY, P.C.
307 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 366-4262

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 6th day of July, 1999.

NEVADA STATE BOARD OF DENTAL EXAMINERS

A. TED TWESME, D.D.S.
President

Law Offices
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302 E. CARSON AVENUE
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LAS VEGAS, NEVADA 89101
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JRL

JHV

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BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

ORDER

Whereas, the above-captioned matter came on for hearing before the Nevada State Board of Dental Examiners (the "Board"), on Friday, October 1, 2010, at that offices of the Board at 6010 South Rainbow Boulevard, Suite A-1, Las Vegas, Nevada 89118, pursuant to a *Notice of Hearing* dated September 10, 2010.

1. The Board appeared by and through the following members who comprised a quorum: William G. Pappas, DDS, President; Donna J. Hellwinkel, DDS, Board Member; James Kinard, DDS, Board Member; J. Stephen Sill, DMD, Board Member; Lisa M. Wark, Public Board Member; Leslea R. Villigan, RDH, Board Member; Masih Soltani, DDS, Board Member; James (Tuko) McKernan, RDH, Board Member (via teleconferencing from Reno, NV); Tony Guillen, DDS, Secretary-Treasurer (via teleconference from Reno, NV), and Rosanne (Missy) Matthews, RDH Board Member (via teleconference from Reno, NV).

2. The Board was represented by Cameron Vandenberg, Deputy Attorney General. John A. Hunt, Esq. appeared for the Complainant. Respondent, John Vennochi, DMD ("Respondent" or

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Suite 500
Las Vegas, Nevada 89169

"Dr. Vennochi"), appeared in person and was represented by and through his attorney, John R. Lusk, Esq. Also present were Kathleen J. Kelly, the Board's Executive Director, and Debra A. Shaffer, the Board's Deputy Executive Director.

3. In pertinent part, the above-referenced *Notice of Hearing* dated September 10, 2010, provides:

> 8. With regards to the above-captioned matter (i.e., Case No. 07-1519), on June 27, 2008, Respondent agreed to and executed *Findings and Recommendations of the Informal Hearing Held Pursuant to NRS 631 and NAC 631 & Consent of John Vennochi, DMD to the Findings and Recommendations Pursuant to N.R.S. § 631.363(5)* (Case No. 07-1519 – approved by the Board on or about June 27, 2008) (hereinafter "June 2008 Order").
>
> 9. In pertinent part, the June 2008 Order provides:
>
> > xiv. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, ~~during the four (4) month suspension period~~ Respondent shall be required to obtain forty (40) additional hours in supplemental education [*two years (2) from adoption of Finding & Recom*]. Twenty (20) hours should be obtained in the area of ethics, and the remaining twenty(20) hours of supplemental education should be received in the area of record keeping. F The Respondent should be required to submit in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board should be required to notify Respondent in writing whether the requested supplemental education is approved for attendance. Respondent agrees seventy (70%) per cent of the supplemental education shall be completed through attendance at live lecture. The remaining thirty (30%) per cent of the supplemental education may be completed through online/home study. Respondent should be required to pay all costs associated with this supplemental education. Respondent should not be allowed to commence the practice of dentistry until Respondent has completed the four (4) month suspension period and has submitted written proof of completion of the recommended supplemental education.

Id., ¶ 6.B.xiv. at 18:12-22 (the italic language is annotated language in the original document).

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Suite 500
Las Vegas, Nevada 89169

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10. Further, the June 2008 Order also provides, in pertinent part, at the "Consent to Findings and Recommendations" section:

> 15. I hereby specifically recognize, acknowledge and agree that failure on my part to fully satisfy all of the terms and conditions of the Findings and Recommendations of the Informal Hearing Officer, shall constitute unprofessional conduct; I further agree in the event I fail to satisfy all of the Findings and Recommendations of the Informal Hearing Officer, the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS.

Id., ¶ 15, at 20:26 to 21:7.

11. Respondent has failed to fully satisfy all of the terms and conditions of the June 2008 Order. Specifically, Respondent has failed to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order.

12. **WHEREFORE, YOU ARE HEREBY GIVEN NOTICE** that the Board has scheduled a public hearing to consider Respondent's failure to fully satisfy all of the terms and conditions of the June 2008 Order in that Respondent has failed to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order. The public hearing is scheduled for **Friday, October 1, 2010,** at **10:00 a.m.** at the offices of the Nevada State Board of Dental Examiners, 6010 South Rainbow Boulevard, Suite A-1, Las Vegas, Nevada 89118.

13. **YOU ARE FURTHER ADVISED** that pursuant to the "Consent to Findings and Recommendations" portion of the July 2008 Order at ¶ 15, 20:26 to 21:7 ("..., the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations..), the purpose of the hearing is to consider Respondent's failure to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order and to determine whether Respondent should be subject to discipline

///

pursuant to NRS 631.350 and/or other relevant and applicable provisions of the Nevada Revised Statutes ("NRS") and/or Nevada Administrative Code ("NAC"), chapters 631 for his failure to comply with said terms/conditions of the June 2008 Order.

Id., at 2:17 to 4:25, at ¶¶ 8-13.

4. The Complainant's Exhibits A-F were offered and admitted. Respondent's Exhibits 1-8 were offered and admitted. Kathleen Kelly and Respondent answered questions under oath. Opening statements and closing arguments were made by the Complainant and Respondent.

5. Respondent, by counsel, stipulated on the record at the October 1, 2010, hearing that he had not completed the required 40 hours of supplemental education requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order; as a consequence, IT IS HEREBY ORDERED that in light of Respondent's stipulation, Respondent is deemed/found to have violated the June 2008 Order.

6. IT IS HEREBY ORDERED that following a motion, the motion being seconded, allowing time for discussion, and by a majority vote that Dr. Vennochi shall be and is hereby granted two (2) additional years to complete the supplemental education requirements referenced at paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order. The additional two (2) years shall be deemed to begin on June 27, 2010.

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7. IT IS FURTHER ORDERED that, pursuant to NRS 622.400, Dr. Vennochi shall pay the Board's attorney's fees and costs relative to this matter, due to his violation of the June 2008 Order.

DATED & DONE this 15th day of OCTOBER, 2010.

NEVADA STATE BOARD OF DENTAL EXAMINERS

WILLIAM G. PAPPAS, DDS, PRESIDENT

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

12B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Y

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Shannon Middle: — Last: Washington

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 15168 Specialty: Emergency Medicine

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Revenge MD

Practice Address: 2610 W Horizon Ridge Pkwy Suite #: 105

City: Henderson State: NV Zip: 89052

Telephone: 702-335-7033 Fax: _____ Email: www.revengemd.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # 3 & 4 **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

#3. In around 2021 I was cited for Aiding and Abetting a non licened Provider. In this case I was the Supervising MD of a Physician Assistant who did not have an Active Nevada licence. The Facility hired her and I did not do my due diligence to make sure she was licensed in Las Vegas. She ended up doing unathorized lipo suction. The case was performed without my knowledge. My licences was placed on probation for 2yrs and I was fined as well as had to take a course.

#4. In 2021-or 2022 mntiple prescriptions weire made of my signitwie. Mutiple copies were made for the drug "phentermine This was done in an office unknow to me. I then lost my controlled licensing ability for 2yrs.

Original Signature (electronic, copies or stamps not accepted)

9/03/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sherman Washington IV MD — 9/3/2024

Print Name (First, Last) — Date

[redacted] — 9/3/2024

Original Signature (electronic, copies or stamps not accepted) — Date

Board Use Only: Date Processed: 9/9/24 Amount: $700 CC

Summary	Attachments
COMPLAINT Case No.: 21-41427-1 August 31, 2021 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Sherman Washington, M.D., alleging five (5) violations of Nevada Revised Statues of (NRS), Chapter 630. Count I: Alleges a violation NRS 630.301(4) Malpractice; Count II: Alleges a violation of NRS 630.305(1)(e) Aiding the Unlicensed Practice of Medicine; Count III: Alleges a violation of NRS 630.306(1)(b)(3) Engaging in Conduct that Violated Pharmacy Board Regulations; Count IV: Alleges a violation of NRS 630.3062(1)(h) Fraudulent, Illegal, Unauthorized and Otherwise Inappropriate Prescribing of Controlled Substances; and Count V: Alleges a violation of NRS 630.306(1)(p) Unsafe or Unprofessional Conduct. Complaint: Twenty-nine (29) pages.	Complaint - 21-41427-1.pdf (/rest/public/data/downloadannotation/index.php?id=6138f259fee73402bc497b20&entity=$2y$10$Q4AHS7pzVTWnvn7gz1e5hOO4xi2GlUcbR3HKIXEY.xJl5g2/
COMPLIANCE Case No. 21-41427-1 December 4, 2023 Completed all terms of the settlement agreement for the above case as of December 3, 2023. ********** **SETTLEMENT AGREEMENT AND ORDER Case No. 21-41427-1 December 3, 2021** On December 3, 2021, the Nevada State Board of Medical Examiners accepted and approved a Settlement Agreement which allowed for an order to be entered finding Dr. Washington violated NRS 630.301(4), NRS 630.305(1)(e), NRS 630.306(1)(b)(3), NRS 630.3062(1)(h) and NRS 630.306(1)(p), as set forth in the Complaint, and ordering that he receive a public reprimand; pay a fine of $5,000.00; complete 22 hours of continuing medical education (CME) related to medical ethics and professionalism, in addition to his statutory CME requirements for licensure; a 24 month probationary period on his license; and to reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him. Settlement Agreement and Order: nine (9) pages.	Settlement Agreement and Order - 21-41427-1.pdf (/rest/public/data/downloadannotation/index.php?id=61b9291681edb569d72d5a92&entity=$2y$10$8hgss07B03GE/rej6HdsKePK1qbUZElhvUlsi9uXX7FVo9WS

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
12/3/21 Sherman Washington, M.D. Dr. Washington's license is placed on probation for a period of 24 months from the date of the Board's acceptance, adoption and approval of this Agreement. During the probation period, should Dr. Washington commit any new violations of the Medical Practice Act or fail to comply with any term or condition of this Agreement, the IC shall be authorized to immediately suspend Dr. Washington's license to practice medicine in Nevada pending an Order to Show Cause Hearing maintaining the suspension pending final adjudication by the Board of the alleged violation. Dr. Washington shall pay a find in the amount of five thousand dollars within sixty days. Dr. Washington shall pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty days in the amount of $2,142.48. Dr. Washington shall complete twenty-two hours of CME regarding medical ethics and professionalism within six months. This is a disciplinary action and is reportable to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.	N/A

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
GRANDE, Megan Colleen	Primary Supervisor	Aug-02-2023
JOHNSON, Logan Daniel	Primary Supervisor	Jan-12-2023
BRISSON, Holly Nicole	Additional Supervisor	Jan-25-2024

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Sherman WASHINGTON Jr.

License Number:
15168

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Feb-07-2014

Expiration Date:
Jun-30-2025

Public Address:
Complete Medical Center 1820 E Lake Mead Blvd Ste M

Public City:
North Las Vegas

Public State:
Nevada

Public ZIP Code:
89030

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Emergency Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Howard Univ College of Medicine / Washington DC	Medical Doctor Degree	N/A	May-11-1985

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Howard University Hospital / Washington DC	Internship	Emergency Medicine	Jul-01-1985	Jun-30-1986
Howard University Hospital / Washington DC	Residency	Emergency Medicine	Jul-01-1986	Jun-30-1988

Board Actions

FILED
SEP 08 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case Nos. 19-243-CS-S** **21-104-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, by and through counsel, Michael Mee, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about April 7, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 21-104-CS-N together with the Statement to Respondent and Notice of Hearing.

3. On or about April 26, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 19-243-CS-S together with the Statement to Respondent and Notice of Hearing.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged herein, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations plead with particularity in each accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) , 21 CFR § 1306.04(a), NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NAC 454.060, by permitting persons not licensed as practitioners in Nevada to fraudulently issue prescriptions for controlled substances and/or dangerous drugs under Respondent's credentials;

B. Respondent violated NRS 453.164(7) and NRS 639.23507 by failing to query the Prescription Monitoring Program (PMP) database;

C. Respondent violated NRS 453.331(1)(e) by failing to disclose administrative actions to the Board on his 2020 biennial renewal application and on his applications for two additional controlled substance registrations;

D. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a), CFR § 1301.71, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS

453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505, NAC 639.742, NAC 453.400 and/or NAC 453.410(1)(d), in the course of operating Vida Spa as detailed in the Nevada State Board of Medical Examiners' order in Case No. 21-41427-1; and

E. Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), (i), (j), (k), (n) and/or (o); and committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1).

8. In order to resolve Case Nos. 19-243-CS-S and 21-104-CS-N without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The certificate of registration of Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, is hereby revoked pursuant to NRS 453.241(l)(b):

1) Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration.;

2) Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of two (2) years from the effective date of this Order; and

3) In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	600.00
Total	**$5,000.00**

Respondent shall make the monthly payments of the fine amount by personal, business, certified or cashier's check or money order made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

C. Pursuant to NRS 622.400, Respondent shall pay:

1) Six Hundred Dollars ($600.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 19-243-CS-S; and

2) Four Thousand Dollars ($4,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 21-104-CS-N.

Respondent shall pay the attorney's fees and costs through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	200.00
Total	**$4,600.00**

Respondent shall make the monthly payments of the attorney's fees and costs by personal, business, certified or cashier's check or money order made payable to the **"Nevada State Board of Pharmacy"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 8, 2022. Respondent or his counsel will appear at the meeting to answer questions from the Board

Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 2 day of September, 2022

SHERMAN WASHINGTON, MD,
Certificate of Registration No. CS24310

Signed this 2nd day of September, 2022

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT this 2nd day of September, 2022

MICHAEL MEE, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, in Case Nos. 19-243-CS-S and 21-104-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 8th day of September, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

FILED
APR - 7 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case No. 21-104-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sherman Washington, MD, held a controlled substance registration, Certificate of Registration No. CS24310, issued by the Board.

FACTUAL ALLEGATIONS

2. While Respondent was the medical director of Revenge MD, located at 10605 Double R Blvd. in Reno, Script #1287 from Respondent's prescription pad for Revenge MD was pre-signed by Respondent, photocopied and used repeatedly by Respondent and/or Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue the following controlled substance prescriptions for patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary:

A. Patient [redacted]
Rx#171143 37.5 MG Phentermine
Rx#171144 500 MG Metformin
Issued and dispensed on 6/25/2021

B. [redacted]
Rx#171806 37.5 MG Phentermine
Rx#171807 500 MG Metformin
Issued and dispensed on 7/02/2021

C. Patient [redacted]
Rx#171460 37.5 MG Phentermine
Issued on 6/29/2021 - not dispensed

D. Patient [redacted]
Rx#170879 37.5 MG Phentermine
Rx#170880 500 MG Metformin
Issued and dispensed on 6/21/2021

E. Patient [redacted]
Rx#170482 37.5 MG Phentermine
Rx#170483 500 MG Metformin
Issued and dispensed on 6/18/2021

F. Patient [redacted]
Rx#171145 37.5 MG Phentermine
Rx#171146 500 MG Metformin
Issued and dispensed on 6/25/2021

G. Patient [redacted]
Rx#170711 37.5 MG Phentermine
Rx#170712 500 MG Metformin
Issued and dispensed on 6/21/2021

H. [redacted]
Rx#171101 37.5 MG Phentermine
Rx#171102 500 MG Metformin
Issued and dispensed on 6/25/2021

I. [redacted]
Rx#170480 37.5 MG Phentermine
Rx#170481 500 MG Metformin
Issued and dispensed on 6/18/2021

J. Patient [redacted]
Rx#172773 37.5 MG Phentermine
Rx#172774 500 MG Metformin
Issued and dispensed on 07/16/2021

K. Patient [redacted]
Rx#172318 37.5 MG Phentermine
Rx#172323 500 MG Metformin
Issued and dispensed on 7/09/2021

L. Patient [redacted]
Rx#172283 37.5 MG Phentermine
Rx#172284 500 MG Metformin
Issued and dispensed on 7/9/2021

M. Patient [redacted]
Rx#171068 37.5 MG Phentermine
Rx#171070 500 MG Metformin
Issued and dispensed on 6/25/2021

N. Patient [redacted]
37.5 MG Phentermine
500 MG Metformin
Pharmacy declined to fill

3. Respondent failed to query the Prescription Monitoring Program (PMP) database between November 16, 2020, and January 19, 2022.

4. On his 2020 biennial renewal application for Certificate of Registration No. CS24310, Respondent failed to disclose to the Board recent administrative actions against him, including, without limitation:

- Arizona Medical Board – Case No. MD-19-1137-A (reprimand/probation)
- State Medical Board of Ohio – Case No. 35.123613 (license revocation)
- Colorado Medical Board – Case No. 2019-8449-B (letter of admonition)
- Georgia Composite Medical Board – Case No. 20220043 (fine)
- Virginia Board of Medicine – Case No. 187506 (license suspension)
- Pennsylvania State Board of Medicine – Case No. 19-49-017073 (reprimand)
- Washington Medical Commission – Case No. W2019-234 (license suspension)
- North Dakota Board of Medicine – Case No. 11222019 (conditions placed on license)

5. On or about December 3, 2021, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 21-41427-1, and placed Respondent's License No. 15168 to practice medicine on probation for engaging in conduct in violation of the standards of practice established by the NSBME, specifically for violation of NRS 630.306(1)((b)(3)) related to engaging in conduct that violates Board regulations, and violation of NRS 630.3062(1)(h), related to the fraudulent, illegal, unauthorized or otherwise inappropriate prescribing, administering or dispensing of a controlled substance listed in schedule II, III or IV, while Respondent was the medical director of Vida Spa, located at 3225 S Rainbow Blvd. #107 and or #206 in Las Vegas.

6. As detailed in the NSBME's order in Case No. 21-41427-1, Respondent permitted persons not licensed as practitioners in Nevada to act under his authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a bona fide therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary.

APPLICABLE LAW

7. No person may possess, administer, furnish, prescribe or dispense a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.232; NRS 453.321(1)(a); NRS 453.377; NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

8. No person may possess, administer furnish, prescribe or dispense a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321; NRS 454.356; NRS 639.100(1); NRS 639.235(1); NRS 639.23505; NAC 639.742.

9. No person may possess, administer furnish, prescribe or dispense a hypodermic device except as authorized by law. NRS 454.480; NRS 454.510; NRS 454.530.

10. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1).

11. A prescription for a controlled substance may be issued only for a legitimate medical purpose and after review of a patient's utilization report in the Prescription Monitoring Program (PMP) database in conformance with NRS 639.23507. 21 CFR § 1306.04(a); NRS 453.381(1).

12. It is a felony offense to falsify a prescription for a controlled substance, falsely representing oneself as a practitioner entitled to write prescriptions, or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.331(1)(c), (d), (f), (h) and (i); NRS 639.281(1); NRS 639.2813(1).

13. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

14. A licensed practitioner who wishes to dispense controlled substances or dangerous drugs must register with the Board. NRS 453.226(1); NRS 454.215(3); NRS 454.356; NRS 639.100(1); NRS 639.23505; NAC 639.742.

15. All controlled substances and dangerous drugs in the possession of a practitioner must be kept in a locked storage area with access restricted to authorized persons. 21 CFR § 1301.71; NAC 453.400; NAC 453.410(1)(d).

16. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

17. NRS 453.164(7) requires each practitioner to review his or her prescriber activity in the Prescription Monitoring Program (PMP) database at least once every 6 months.

18. Supplying or diverting drugs or devices which are legally sold in pharmacies so that unqualified persons can circumvent any law pertaining to the legal sale of such articles constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

20. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person not licensed to practice in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

23. Prescribing or dispensing a drug to any patient with whom the prescribing or dispensing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

24. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

25. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

26. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

27. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

28. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

29. By fraudulently issuing controlled substance prescriptions as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

30. By fraudulently issuing controlled substance prescriptions as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1) and/or NRS 639.235(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of State Law - Prescription Monitoring Program

31. By failing to query the Prescription Monitoring Program (PMP) database between November 16, 2020, and January 19, 2022, to review a patient's utilization report prior to issuing a prescription for a controlled substance and to review his prescriber activity, as

alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.164(7) and NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT FOUR

Furnishing False Material Information to Board

32. By failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.331(1)(e), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT FIVE

Obtaining Registration by False or Fraudulent Application

33. By failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), and/or NRS 639.210(10).

COUNT SIX

Violation of Federal Controlled Substances Act – Unlawful Operation of Vida Spa

34. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 21-41427-1, and permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances to patients with whom Respondent had not established a *bona fide* therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a controlled substance was medically necessary, Respondent violated, attempted to violate, assisted or abetted in the violation of or

conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT SEVEN

Violation of State Law – Unlawful Operation of Vida Spa

35. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 21-41427-1, and permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa, to provide on-site medical treatment to patients, and to purchase, access, store, possess, administer, furnish and/or dispense controlled substances, dangerous drugs and hypodermic devices to patients with whom Respondent had not established a *bona fide* therapeutic relationship, before Respondent had examined the patients and without his direct supervision, and for whom Respondent had neither diagnosed or determined that a prescription drug was medically necessary, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS 453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505 and/or NAC 639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Dispensing Without a Valid Registration

36. By dispensing controlled substances and dangerous drugs in the course of operating Vida Spa without a valid dispensing practitioner registration as detailed in the NSBME's order in Case No. 21-41427-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.266(1); NRS 453.321(1)(a); NRS 454.215(3), NRS 454.221, NRS 454.356, NRS 639.100(1), NRS 639.23505 and/or NAC

639.742, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT NINE

Permitting Unrestricted Access to Drug Inventory

37. By permitting persons not licensed as practitioners in Nevada to have unrestricted access to the inventory of controlled substances and dangerous drugs in the course of operating Vida Spa, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71, NAC 453.400 and/or NAC 453.410(1)(d), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT TEN

Unprofessional Conduct – Diversion

38. By permitting Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue controlled substance prescriptions as alleged in paragraph 2 herein, and by permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent supplied and/or diverted drugs or devices which are legally sold in pharmacies so that unqualified persons can circumvent any law pertaining to the legal sale of such articles and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

39. By fraudulently issuing controlled substance prescriptions as alleged in paragraph 2 herein, by failing to disclose the administrative actions to the Board on his 2020 biennial renewal application as alleged in Paragraph 4 herein, and by permitting persons not licensed as

practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWELVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

40. By his acts as alleged herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT THIRTEEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

41. By permitting Revenge MD staff not licensed as practitioners in Nevada to fraudulently issue controlled substance prescriptions as alleged in paragraph 2 herein, and by permitting persons not licensed as practitioners in Nevada to act under Respondent's authority to operate Vida Spa as detailed in the NSBME's order in Case No. 21-41427-1, Respondent aided and abetted unlicensed practice and engaged in unprofessional conduct as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FOURTEEN

Unprofessional Conduct – Dispensing without a Valid Registration

42. By dispensing controlled substances and dangerous drugs in the course of operating Vida Spa without a valid dispensing practitioner registration as detailed in the NSBME's order in Case No. 21-41427-1, Respondent engaged in unprofessional conduct and

conduct contrary to the public interest as defined in NAC 639.945(1)(k), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIFTEEN

Unprofessional Conduct – Prescribing/Dispensing Without Bona Fide Therapeutic Relationship

43. By unlawfully prescribing and dispensing controlled substances and dangerous drugs to patients with whom he did not have a bona fide therapeutic relationship as alleged in paragraph 2 herein and as detailed in the NSBME's order in Case No. 21-41427-1, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(n) and (o), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SIXTEEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

44. By his acts as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 7th day of April 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

FILED
APR 26 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. LAS VEGAS SCRIPTS RX, Pharmacy License No. PH03930, NATHAN EDOUARD, RPH, Certificate of Registration No. 19462, and SHERMAN WASHINGTON, MD, Certificate of Registration No. CS24310, Respondents.	CASE NOS. 19-243-PH-S 19-243-RPH-S 19-243-CS-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Las Vegas Scripts Rx ("LV Scripts") held a Nevada Pharmacy License No. PH03930, Respondent Nathan Edouard, RPh, ("Edouard") held a Nevada Pharmacist Certificate of Registration No. 19462, and Respondent Sherman Washington, MD, ("Washington") held a Controlled Substance Registration No. CS24310, all issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent LV Scripts is a pharmacy located at 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription. The ingredients and percentages of each drug were not identified on the prescription label.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts was shipping prescriptions to California and Arizona where LV Scripts is not licensed.

b. LV Scripts appeared to be filling faxed prescriptions that were not signed by practitioners, but contained copied signatures.

c. LV Scripts did not include the required documentation on prescriptions received by telephone from practitioners. The prescriptions also lacked the name(s) of the person(s) who telephoned the prescription, the date(s) the prescription(s) were received and/or the name(s) of the pharmacist(s) who received the order(s).

d. LV Scripts is providing pre-printed prescription forms for marketing purposes in efforts to promote sales to patients and/or practitioners.

e. Respondent Eduoard was improperly documenting prescriptions received by telephone orders on transferred prescriptions.

APPLICABLE LAW

7. A pharmacy must be managed by a registered pharmacist who is responsible for compliance by the pharmacy and personnel with all state, and federal laws and regulations regarding the operation of the pharmacy. NRS 639.220(1).

8. Unprofessional conduct includes a licensee failing strictly to follow the instructions of the prescribing practitioner in filling of and/or placing contents on the label of the prescription. NRS 585.485(2)(b)(1); NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

9. Unprofessional conduct includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

10. Unprofessional conduct includes a licensee performing any act, task, or operation for which licensure, certification, or registration is required without the required licensure, certification, or registration. NAC 639.945(1)(k).

11. Unprofessional conduct includes the use of secret formulas and failure to strictly follow the instructions of the person writing, making, or ordering a prescription, and to specify the content on the label of the prescription. NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

12. No pharmacist or owner of a pharmacy may offer an unearned rebate. The furnishing to a practitioner by a pharmacist or pharmacy of prescription blanks bearing the name and address of the pharmacy is an unearned rebate. NRS 639.264.

13. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230; NAC 639.702; NAC 639.945.

14. Respondents are subject to discipline for violations pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

COUNT ONE

Unprofessional Conduct – Failure to Strictly Follow Instructions of Prescribing Practitioner (Respondent Edouard)

15. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful and Negligent Conduct (Respondents Edouard and Washington)

16. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

17. Respondent Washington engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he allowed his copied signature to be used on prescriptions in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

COUNT THREE

Failure to Properly Document Prescriptions on Telephoned Orders (Respondent Edouard)

18. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.707(1), (2), and (6)(b), and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

COUNT FOUR

Unprofessional Conduct – Utilization of Pre-printed Forms as Unearned Rebate (Respondent Edouard)

19. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT FIVE

Unprofessional Conduct – Unlicensed Activity (Respondent Edouard)

20. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he shipped prescriptions to California and Arizona without valid licenses in those jurisdictions in violation of NAC 639.945(1)(k), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT SIX

Pharmacy/Pharmacy Owner Responsibility (Respondent LV Scripts)

21. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license(s)/registration(s) of these Respondents.

Signed this 26th day of APRIL 2022.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
PHONE (775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

May 18, 2021

VIA CERTIFIED U.S. MAIL

Sandra Bledsoe
Revenge MD
10605 Double R Blvd.
Reno, NV 89521

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada (Case No. 21-042-C-S)

Dear Ms. Bledsoe:

The Nevada State Board of Pharmacy (Board) has determined that in the course of your ownership and operation of Revenge MD at 10605 Double R Blvd. in Reno you are engaged in unlicensed activity as follows:

1. You unlawfully purchase, store, possess, administer, furnish and/or dispense dangerous drugs, specifically cosmetic injectable fillers including, without limitation, Restylane Kysee, Restylane Lidocaine, Restylane Lyft, Juvederm Voluma with Lidocaine and/or and Liporase, to patients who have not been examined by a practitioner. You unlawfully provide on-site medical treatment to patients, including the administration of dangerous drugs through cosmetic injections, without direct practitioner supervision. This constitutes a violation of state law, including, without limitation, NRS 454.213(1), NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356; NRS 639.100(1), NRS 639.281(1), NRS 639.282(1)(d), NAC 639.601(1) and/or NAC 639.898(1).
2. You are engaged in the business of shipping, receiving, storing and distributing prescription drug products into and within Nevada without a license to engage in business as a wholesaler. This constitutes a violation of federal and State law, including, without limitation, 21 U.S. Code § 353(e)(1), 21 CFR Part 205, NRS 639.100, NRS 639.233, NRS 639.285 and NAC 639.585-.607.
3. Some of the drug products involved are intended for distribution in foreign markets and are not approved for marketing, distribution or use in the U.S. This constitutes a violation of federal law, including, without limitation, 21 U.S.C. § 331 and 21 U.S.C. § 355(a), and consequently a violation of NRS 454.351(1).

This notice shall serve as a CITATION pursuant to NRS 639.2895(2) for unlicensed activity. The Board has assessed an administrative fine of ten thousand dollars ($10,000.00) pursuant to NRS 639.2895(3). You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check, certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

9171 9690 0935 0252 0575 07

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Please be aware that the forgoing does not preclude the filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,



Brett Kandt
General Counsel
Nevada State Board of Pharmacy

cc: Bret Whipple, Esq.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18st day of May, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sandra Bledsoe
Revenge MD
10605 Double R Blvd
Reno, NV 89521

Bret Whipple, Esq.
1100 S. 10th Street
Las Vegas, NV 89104

KRISTOPHER MANGOSING

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
PHONE (775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

May 18, 2021

VIA CERTIFIED U.S. MAIL

Sandra Bledsoe
Revenge MD
2405 W. Horizon Ridge Pkwy #100
Henderson, Nevada 89052

Re: CEASE and DESIST/CITATION: Unlicensed Activity in Nevada (Case No. 21-042-B-S)

Dear Ms. Bledsoe:

The Nevada State Board of Pharmacy (Board) has determined that in the course of your ownership and operation of Revenge MD at 2405 W. Horizon Ridge Pkwy #100 in Henderson in Reno you are engaged in unlicensed activity as follows:

1. You unlawfully purchase, store, possess, administer, furnish and/or dispense dangerous drugs, specifically cosmetic injectable fillers including, without limitation, Restylane Kysee, Restylane Lidocaine, Restylane Lyft, Juvederm Voluma with Lidocaine and/or and Liporase, to patients who have not been examined by a practitioner. You unlawfully provide on-site medical treatment to patients, including the administration of dangerous drugs through cosmetic injections, without direct practitioner supervision. This constitutes a violation of state law, including, without limitation, NRS 454.213(1), NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356; NRS 639.100(1), NRS 639.281(1), NRS 639.282(1)(d), NAC 639.601(1) and/or NAC 639.898(1).
2. You are engaged in the business of shipping, receiving, storing and distributing prescription drug products into and within Nevada without a license to engage in business as a wholesaler. This constitutes a violation of federal and State law, including, without limitation, 21 U.S. Code § 353(e)(1), 21 CFR Part 205, NRS 639.100, NRS 639.233, NRS 639.285 and NAC 639.585-.607.
3. Some of the drug products involved are intended for distribution in foreign markets and are not approved for marketing, distribution or use in the U.S. This constitutes a violation of federal law, including, without limitation, 21 U.S.C. § 331 and 21 U.S.C. § 355(a), and consequently a violation of NRS 454.351(1).

This notice shall serve as a CITATION pursuant to NRS 639.2895(2) for unlicensed activity. The Board has assessed an administrative fine of ten thousand dollars ($10,000.00) pursuant to NRS 639.2895(3). You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

9171 9690 0935 0252 0575 14

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Please be aware that the forgoing does not preclude the filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,



Brett Kandt
General Counsel
Nevada State Board of Pharmacy

cc: Bret Whipple, Esq.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18st day of May, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sandra Bledsoe
Revenge MD
2405. W Horizon Ridge Pkwy #100
Henderson, NV 89052

Bret Whipple, Esq.
1100 S. 10th Street
Las Vegas, NV 89104

KRISTOPHER MANGOSING

12C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

4

CS26115

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☐ Schedule V

Section 1: Personal Information

First: Victor Middle: Jimenez Last: Bonuel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: NV Zip: 89012

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 7208 Specialty: [redacted]

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled sub[redacted]

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Dr. Dara Forte Family Practice

Practice Address: 9010 West Cheyenne Ave Suite #:

City: Las Vegas State: NV Zip: 89129

Telephone: 7022408646 Fax: 702 240 0206 Email: dforte@fortefamilypractice.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Victor Samuel [redacted]

Print Name (First, Last)

8-22-2024

Date

Original Signature (electronic, copies or stamps not accepted)

8-22-2024

Date

Board Use Only: Date Processed: 9/17/24 Amount: ~~$600.00~~

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Oct 2023 / Pending		AL	Montgomery	
Case # 5		Governing, licensing, Arresting Presiding Body/Agency/Court: Pending review attached documents		
Reason/Charge: Suspension of AL Board of Pharmacy License				
Plaintiff/Defendant/Claimant/Respondent: AL Medical Boards		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity: American Family Care				

Provide explanation below:

#3. Ive to give up my Controlled Substance license in Alabama in Jan. 2024 due to. Infractions e.g. Not doing urine drug screens on patients, Not checking the PDMP profiles on all patients, etc Subsequently the DEA in Alabama told me to surrender my DEA license (# BB3732371). Over 2000 Alabama Doctors have to Surrender their Controlled Substances DEA licenses due to multiple reasons including above statements. Sometime in February, I decided to voluntarily Surrender my AL Board of Pharmacy License as well as my DEA license. I decided not to fight the Alabama Medical Board case + not attend their hearing.

Original Signature (electronic, copies or stamps not accepted) — Date: Aug 22, 2024 / Sept 30, 2024

BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
-vs-	)	**CASE NO. 2023 - 22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

ORDER DISMISSING PROCEEEDING

The Alabama State Board of Medical Examiners dismisses the order to show cause previously set for hearing on February 22, 2024, for the reasons stated below.

On February 14, 2024, Victor Jimenez Bonuel, M.D., voluntarily surrendered his Alabama Controlled Substances Certificate. See Motion to Dismiss, Exhibit A.

Done and Ordered in Montgomery, Alabama, on March 4, 2024.

Mark H. LeQuire, M.D.
Chairman, Alabama State Board of Medical Examiners

CC: BY ELECTRONIC MAIL ONLY
E. Wilson Hunter, Esq.
Alicia Harrison, Esq.

By FedEx Commercial Carrier
Victor Jimenez Bonuel, M.D.
[redacted]

By Electronic Mail
[redacted]

BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
v.	)	**CASE NO.: 2023-22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

MOTION TO DISMISS

The Alabama State Board of Medical Examiners ("the Board"), by and through its counsel of record, moves to dismiss the Order to Show Cause previously filed in this matter by the Board on November 13, 2023. As grounds for this motion, the Board states that Respondent Victor Jimenez Bonuel, M.D. executed a Voluntary Surrender of Alabama Controlled Substances Certificate on February 14, 2024. *See* **Exhibit A.**

WHEREFORE, the Board requests the hearing officer, Honorable William Gordon, to enter an order dismissing this action.

Respectfully submitted on this the 1st day of March, 2024.

s/ Alicia Harrison
Alicia Harrison
Associate General Counsel
ALABAMA STATE BOARD OF MEDICAL EXAMINERS
PO Box 946
Montgomery AL 36101-0946
[redacted]

CERTIFICATE OF SERVICE

I hereby certify that I have on this 1st day of March, 2024, served a copy of the foregoing pleading upon the following, *via* electronic or U.S. Mail:

Victor Jimenez Bonuel, M.D.
[redacted]

Honorable William R. Gordon
[redacted]

Current address & emails:
[redacted]

s/ Alicia Harrison
OF COUNSEL

[redacted]

From: BME
Sent: Thursday, February 15, 2024 3:24 PM
To: [redacted]
Subject: FW: Dr Bonuel
Attachments: IMG_6854.HEIC; IMG_6853.HEIC

From: [redacted]
Sent: Thursday, February 15, 2024 1:21 PM
To: BME <bme@albme.gov>; [redacted]
Subject: Dr Bonuel

You don't often get email from [redacted] Learn why this is Important

Hello,
I'm voluntarily giving up my ACSC . I'm cancelling our meeting on February 22,2024.

Thank you.

Dr Bonuel
[redacted]

Warning EXTERNAL EMAIL
This message has originated from outside albme.gov. Do not click links or open attachments unless you recognize the sender and never give out your password.

STATE OF ALABAMA)

MONTGOMERY COUNTY)

VOLUNTARY SURRENDER OF ALABAMA CONTROLLED SUBSTANCES CERTIFICATE

After being fully advised of my rights, and understanding that I am not required to surrender my controlled substances privileges, I freely execute this document and choose to take the actions described herein.

I, VICTOR JIMINEZ BONUEL, M.D., hereby knowingly, freely, and voluntarily surrender any authority under my Alabama Controlled Substances Certificate, ACSC number ACSC.38778, to order, manufacture, distribute, possess, dispense, administer or prescribe Schedule II, IIN, III, IIIN, IV and/or V controlled substances. I acknowledge that this action is taken by me while under investigation by the Alabama Board of Medical Examiners relating to my prescribing of controlled substances.

I understand and acknowledge I will have no authority to order, dispense, distribute, administer, or prescribe controlled substances in the state of Alabama.

I further understand and acknowledge that this surrender shall be effective immediately upon execution.

I acknowledge that I sign this document willingly and that I execute it as my free and voluntary act for the purposes herein expressed, and that I am of sound mind and under no constraint or undue influence. I understand that I have a right to a hearing in this matter, and I hereby freely, knowingly, and voluntarily waive such right to a hearing.

I also understand that the Alabama State Board of Medical Examiners shall [illegible] to any investigative file in this matter should I request reinstatement of my ACSC and that the Board has the right to contest my reinstatement. I understand that the Board may summarily deny any petition for reinstatement for two (2) years from the effective date of the surrender of my ACSC. I further understand that upon application for reinstatement, it shall be my burden to prove by sufficient evidence that I qualify for reinstatement as provided for in the Board's rules, which includes, but not limited to, demonstrating to the satisfaction of the Board that I can practice medicine with reasonable skill and safety to patients.

I further acknowledge that this voluntary surrender constitutes a public record of the Alabama State Board of Medical Examiners and will be reported by the Board to the National Practitioner Data Bank and to the Federation of State Medical Boards. This voluntary surrender may be released by the Alabama State Board of Medical Examiners to any person or entity requesting information concerning the licensure status in Alabama of the physician named herein.

EXECUTED this 14th day of February, 2024.

[redacted]

VICTOR JIMINEZ BONUEL, M.D.

Witnessed by:

(Print) Nida Bonuel (Sign) [redacted]

Victor Jimenez BONUEL

License Number:
7208

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Jul-28-1994

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Henderson

Public State:
Nevada

Public ZIP Code:
89012

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Internal Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Far Eastern University / Manila, Philippines	Medical Doctor Degree	N/A	Apr-05-1983

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Woodhull Medical & Mental Health Ctr/ Brooklyn, NY	Residency	Internal Medicine	Jul-01-1990	Jun-30-1993

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Powered by Thentia Cloud (https://www.thentia.com)

From:	Monica Moazez
To:	Darlene Nases
Subject:	FW: Information About Victor Jimenez Bonuel
Date:	Tuesday, December 17, 2024 8:04:38 AM
Attachments:	image001.png

From: Carla Kruger <ckruger@albme.gov>
Sent: Tuesday, December 17, 2024 7:52 AM
To: Monica Moazez <moazez@pharmacy.nv.gov>
Subject: RE: Information About Victor Jimenez Bonuel

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good morning,

The only public docs will be the Order to Show Cause/Order Temporarily Suspending ACSC from Nov. 2023, the voluntary surrender of ACSC, and the Order dismissing the Order to Show Cause due to the surrender. The violation allegations are stated in the Order to Show Cause.

This all had to do with his Alabama Controlled Substances Certificate and his ability to prescribe controlled substances. His license remains active, is full and unrestricted, and he was approved for a collaborative practice with Ashley Pauldin, CRNP. He has not requested for reinstatement of his ACSC.

I hope this helps. Please give me a call today before 2:00 or this Thursday/Friday anytime if you would like to discuss. The only additional item I'd be able to provide with a release is the minute entry extracts which don't say anything in additional to what was in the public documents.

Carla H. Kruger | *Public Information Officer*

Office of the General Counsel
Alabama Board of Medical Examiners
P.O. Box 946, Montgomery, AL 36101
Direct: 334-833-0172
Email: ckruger@albme.gov

From: Monica Moazez <moazez@pharmacy.nv.gov>
Sent: Monday, December 16, 2024 6:13 PM
To: Carla Kruger <ckruger@albme.gov>
Subject: RE: Information About Victor Jimenez Bonuel

Carla,

Thank you for getting back to me and for clarifying about the petition for reinstatement. I do not currently have a release from Dr. Bonuel; however, I should be able to get his consent. He knows the Board has requested more information from him and appears to be cooperative—there just seems to be a bit of a language barrier issue. Attached is what he submitted to me but as far as I can tell, there should be other public documents in addition to what he's sent me. Are you aware of any? I can also absolutely give you a call tomorrow—whatever is easiest.

Monica Moazez
Assistant General Counsel
Nevada State Board of Pharmacy
(702) 486-6420, Ext. 151

Confidentiality Notice: This email and any attachments are confidential. If you are not the intended recipient, please notify me immediately by replying to this email and deleting the original message and any copies from your system. Thank you.

From: Carla Kruger <ckruger@albme.gov>
Sent: Friday, December 13, 2024 7:47 AM
To: Monica Moazez <moazez@pharmacy.nv.gov>
Subject: RE: Information About Victor Jimenez Bonuel

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good morning Ms. Moazez, your email was forwarded to this department for response.

Do you have a release from Dr. Banuel that would allow me to share confidential information so that I can share more?

As to the voluntary surrender, the wording about the Board being able to summarily a petition to reinstate his ACSC, that only applies to Alabama.

Please let me know if I can provide any additional information that is public or, if you can send me a recent (no older than one year) release, I can tell you more. The details are pretty much all in the public documents, though.

Feel free to give me a call to discuss if that is easier. My direct line is below.

Warm regards,

Carla H. Kruger | *Public Information Officer*

Office of the General Counsel
Alabama Board of Medical Examiners
P.O. Box 946, Montgomery, AL 36101
Direct: 334-833-0172
Email: ckruger@albme.gov

From: Julee Cranmore <jcranmore@albme.gov>
Sent: Thursday, December 12, 2024 4:55 PM
To: Carla Kruger <ckruger@albme.gov>; Lynde Crowder <lcrowder@albme.gov>
Subject: FW: Information About Victor Jimenez Bonuel

Please see below.

Thank you,

Julee Cranmore
Credentialing Specialist
Alabama Board of Medical Examiners
848 Washington Avenue (36104)
PO Box 946
Montgomery, AL 36101-0946
Telephone: (334) 242-4116
Direct Dial: (334) 604-4959
jcranmore@albme.gov

From: Monica Moazez <moazez@pharmacy.nv.gov>
Sent: Wednesday, December 11, 2024 6:09 PM
To: BME <bme@albme.gov>; Credentialing <credentialing@albme.gov>
Subject: Re: Information About Victor Jimenez Bonuel

Some people who received this message don't often get email from moazez@pharmacy.nv.gov. Learn why this is important

Good afternoon,

I serve as counsel for Nevada's Pharmacy Board and am reaching out in the hopes of collecting much needed information related to a prior licensee, Victor Jimenez Bonuel. He has applied for his CS license here in Nevada and has appeared at our December Board Meeting. However, at that meeting, the Board and I concluded that we needed more information about the voluntary surrender of his license on February 14, 2024 with your Board. He has provided the attached information/disclosures to me for review, but they still appear to be incomplete. Furthermore, the voluntary surrender agreement on page 14 seems to indicate that your Board can deny any petition for his reinstatement for two years after the surrender of his ACSC. Does that apply only to Alabama or is that a broad restriction? I'm doing my best to fill in the gaps for our Board as he will reappear at our next Board meeting in January. Any help you can provide would be greatly appreciated.

Thank you,

Monica Moazez
Assistant General Counsel
Nevada State Board of Pharmacy
(702) 486-6420, Ext. 151

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*****Warning EXTERNAL EMAIL*****

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BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
-vs-	)	**CASE NO. 2023 - 22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

ORDER DISMISSING PROCEEEDING

The Alabama State Board of Medical Examiners dismisses the order to show cause previously set for hearing on February 22, 2024, for the reasons stated below.

On February 14, 2024, Victor Jimenez Bonuel, M.D., voluntarily surrendered his Alabama Controlled Substances Certificate. See Motion to Dismiss, Exhibit A.

Done and Ordered in Montgomery, Alabama, on March 4, 2024.

Mark H. LeQuire, M.D.
Chairman, Alabama State Board of Medical Examiners

CC: BY ELECTRONIC MAIL ONLY
E. Wilson Hunter, Esq.
Alicia Harrison, Esq.

By FedEx Commercial Carrier
Victor Jimenez Bonuel, M.D.
[redacted] Aaron Arnov Drive
Fairfield, AL 35064

By Electronic Mail
[redacted]

EXHIBIT A

BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
v.	)	**CASE NO.: 2023-22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

MOTION TO DISMISS

The Alabama State Board of Medical Examiners ("the Board"), by and through its counsel of record, moves to dismiss the Order to Show Cause previously filed in this matter by the Board on November 13, 2023. As grounds for this motion, the Board states that Respondent Victor Jimenez Bonuel, M.D. executed a Voluntary Surrender of Alabama Controlled Substances Certificate on February 14, 2024. *See* **Exhibit A**.

WHEREFORE, the Board requests the hearing officer, Honorable William Gordon, to enter an order dismissing this action.

Respectfully submitted on this the 1st day of March, 2024.

s/ Alicia Harrison
Alicia Harrison
Associate General Counsel
ALABAMA STATE BOARD OF MEDICAL EXAMINERS
PO Box 946
Montgomery AL 36101-0946
334-833-0167
aharrison@albme.gov

CERTIFICATE OF SERVICE

I hereby certify that I have on this 1st day of March, 2024, served a copy of the foregoing pleading upon the following, *via* electronic or U.S. Mail:

Victor Jimenez Bonuel, M.D.
[redacted] Aaron Arnov Drive
Fairfield, AL 35064
[redacted]

Honorable William R. Gordon
wrgordon@charter.net

s/ Alicia Harrison
OF COUNSEL

EXHIBIT A

Christy Lawson

From: BME
Sent: Thursday, February 15, 2024 3:24 PM
To: Christy Lawson
Subject: FW: Dr Bonuel
Attachments: IMG_6854.HEIC; IMG_6853.HEIC

From: Vic Bonwell [redacted]
Sent: Thursday, February 15, 2024 1:21 PM
To: BME <bme@albme.gov>; [redacted]; [redacted]
Subject: Dr Bonuel

You don't often get email from [redacted]@yahoo.com. Learn why this is important

Hello,
I'm voluntarily giving up my ACSC . I'm cancelling our meeting on February 22,2024.

Thank you.

Dr Bonuel
[redacted]

Warning EXTERNAL EMAIL
This message has originated from outside albme.gov. Do not click links or open attachments unless you recognize the sender and never give out your password.

STATE OF ALABAMA)
)
MONTGOMERY COUNTY)

VOLUNTARY SURRENDER OF
ALABAMA CONTROLLED SUBSTANCES CERTIFICATE

After being fully advised of my rights, and understanding that I am not required to surrender my controlled substances privileges, I freely execute this document and choose to take the actions described herein.

I, VICTOR JIMINEZ BONUEL, M.D., hereby knowingly, freely, and voluntarily surrender any authority under my Alabama Controlled Substances Certificate, ACSC number ACSC.38778, to order, manufacture, distribute, possess, dispense, administer or prescribe Schedule II, IIN, III, IIIN, IV and/or V controlled substances. I acknowledge that this action is taken by me while under investigation by the Alabama Board of Medical Examiners relating to my prescribing of controlled substances.

I understand and acknowledge I will have no authority to order, dispense, distribute, administer, or prescribe controlled substances in the state of Alabama.

I further understand and acknowledge that this surrender shall be effective immediately upon execution.

I acknowledge that I sign this document willingly and that I execute it as my free and voluntary act for the purposes herein expressed, and that I am of sound mind and under no constraint or undue influence. I understand that I have a right to a hearing in this matter, and I hereby freely, knowingly, and voluntarily waive such right to a hearing.

I also understand that the Alabama State Board of Medical Examiners shall have access to any investigative file in this matter should I request reinstatement of my ACSC, and that the Board has the right to contest my reinstatement. I understand that the Board may summarily deny any petition for reinstatement for two (2) years from the effective date of the surrender of my ACSC. I further understand that upon applying for reinstatement, it shall be my burden to prove by sufficient evidence that I satisfy the criteria for reinstatement as provided for in the Board's rules, which include, but are not limited to, demonstrating to the satisfaction of the Board that I am able to practice medicine with reasonable skill and safety to patients.

I further acknowledge that this voluntary surrender constitutes a public record of the Alabama State Board of Medical Examiners and will be reported by the Board to the National Practitioner Data Bank and to the Federation of State Medical Boards. This voluntary surrender may be released by the Alabama State Board of Medical Examiners to any person or entity requesting information concerning the licensure status in Alabama of the physician named herein.

EXECUTED this 14th day of February, 2024.

VICTOR JIMINEZ BONUEL, M.D.

Witnessed by:

(Print) Nida Bonuel (Sign) NBonuel

13

13A

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee :	$200.00
Convenience Fee :	$10.00
License Number :	CS09880
License Type :	Controlled Substance
New Expiration Date :	10/31/2026

Personal Information

First Name : DANA

Middle (initial only) :

Last Name : MARKS

License # : CS09880

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Humboldt ER

Military Address : ☐

Street : 118 E HASKELL ST

Country : United States

City : WINNEMUCCA State : Nevada Zip : 89445

Practice Phone : (XXX) XXX-XXXX

Cell Phone : [redacted]

Email Address : [redacted]

Sex : Male

Child Support Information – Check appropriate answer

- ◉ I am **NOT SUBJECT** to a court order for the support of a child.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.
- ○ Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)
- ○ Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	○ Yes ◉ No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	○ Yes ◉ No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	○ Yes ◉ No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? (●) Yes ( ) No

Please see legal question 2 document

Document Name	Document Type	Date	Link	Action
No Record Found				

Document Name :

Document Type : -Select DocumentType-

Document : Drop file here to upload or click here to browse and select file(s) to upload.

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2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? (●) Yes ( ) No

Nevada State Board of Pharmacy
Supporting document for questions 1 and 2
Oct. 21, 2024
Re; Dana R. Marks, MD

I have been board-certified in emergency medicine and working almost exclusively working in emergency departments for 28 years. I ha ve also had an active state medical license with the State Board of Medical Examiners for almost the same amount of time.

September 22, 2022 I was finishing a series of shifts at Battle Mountain General Hospital emergency room. The day before in the afte rnoon a full school bus was hit broadside at approximately 60 miles an hour. On scene I was able to assist the paramedics in pronoun cing one individual's death and having to Care Flight two others to Reno. The following 24 hours I attended to consoling children and parents, reading x-rays and suturing lacerations.

I started my return trip to Reno at approximately 3:00 in the afternoon. Approximately 8 PM that evening, I entered the city of Fallo n and was promptly pulled over, due to a nonworking taillight of which I was unaware. The officer asked if I had been drinking, I tol d her no, but explained that I had been up for the past 36 hours without sleep. She then told me that she was asking because she noti ced that I was "blinking slowly" and that I was slow to respond to her questions. She asked if I would blow into her breathalyzer, bu t because I had been eating mint flavored candies, I asked for a blood test instead of the breathalyzer. At this point, the tone of our interaction changed significantly, becoming more confrontational.

I submitted to a field sobriety test, which she informed me I failed. She then placed me under arrest and proceeded with warrants for searching my car and for obtaining blood toxicology, which I had already requested. Upon entering the jail for the mandatory 12 hour s to sober up, my breathalyzer registered zero on admission and upon release.

The officers search of my SUV produced drug paraphernalia, and a small amount of methamphetamines, which belong to a friend who had b orrowed my car a few days before. She wrote a heartfelt letter to the judge, explaining her ownership. But according to the courts p ossession is ownership. (and methamphetamine was present in my blood tox report as well). December 13, 2022 the toxicology report w as resulted and showed no alcohol in my system. So more toxicology testing was requested, and was resulted in May, 2023 showing a sma ll amount of methamphetamines in my system.

I accepted a plea deal which resulted in a misdemeanor DUI and a misdemeanor possession of controlled substance conviction. June 16, 2023 my sentencing requirements were 36 hours of community service, completion of DUI school level one course, participation in a vic tims impact panel, and payment of the usual fines and fees for a first time (and only) DUI conviction. All requirements have been ful filled.
October 15, 2022 I voluntarily entered a monitoring and treatment program with Misty Guantonio with Individual counseling, a group s upport meeting and random drug testing. This evolved into the PRN monitoring and treatment program with Mark Chase. On June 1, 2023, I signed a confidential, non-disciplinary, stipulation with the NSBME investigative committee requires me to continue my participatio n in the PRN monitoring and treatment program which provides regular reports to the NSBME (and will be soon to the DEA). I am in full compliance.

I also was fully forthcoming with this process with the DEA during my license renewal last year and we are in the process of finalizi ng a Memorandum of Agreement, continuation of similar terms with PRN.

Should you require any further information, at this time, please don't hesitate to contact me at; [redacted] or [redacted].

Also Lyn E. Beggs, Esq. would be a valued source as well, [redacted].

Respectfully,
Dana R. Marks, MD, ABEM

Document Name	Document Type	Date	Link	Action
No Record Found				

Document Name :

Document Type : -Select DocumentType-

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

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Criminal Action :

State : Nevada Date : 06/16/2023

Case # : [redacted]

County : Churchill Court : New River Township

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? ○ Yes ◉ No

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ○ Yes ◉ No

DEA Registration

Please upload a copy of your current DEA Registration associated with the Controlled Substance Registration you are renewing.

Document Name	Document Type	Date	Link	Action
BM5206405	NV DEA Certificate	10/24/2024	Document Details	

Document Name : Document Type : NV DEA Certificate

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Acknowledgement and Declaration

☑ I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

By signing and submitting this renewal application, I certify that: 1. I hold an active and current Nevada license with my professional licensing board, and 2. My DEA certificate is CURRENT and reflects my current NV practicing address.

Signature : DANA MARKS Date Of Application : 10/24/2024

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2024 to 10/31/2026	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : 120715892900

InvoiceDate : 10/24/2024

Paid

Pay & Submit

13B

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee :	$200.00
Convenience Fee :	$15.00
License Number :	CS30299
License Type :	Controlled Substance
New Expiration Date :	10/31/2026

Personal Information

First Name : Steven

Middle (initial only) : Thomas

Last Name : Huerta

License # : CS30299

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Four Square Clinicals

Military Address : ☐

Street : 100 N. Arlington Ave, 340A

Country : United States

City : Reno

State : Nevada

Zip : 89501

Practice Phone : (775) 238-3082

Cell Phone : [redacted]

Email Address : [redacted]

Sex : Male

Child Support Information – Check appropriate answer

- ◉ I am **NOT SUBJECT** to a court order for the support of a child.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.
- ○ Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)
- ○ Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	○ Yes ◉ No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	○ Yes ◉ No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	○ Yes ◉ No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? ◉ Yes ○ No

I was contracted in California with a group that was found to be in a fraudulent scheme with the FQHC, local pharmacy and another specialty group. While I left the site that triggered the investigation, the charts audited were from the time I was at that facility. The initial DCHS case was appealed and I won but it triggered an Orange County attorney general and BRN investigations. My case with the attorney general was dismissed and I am now a potential state witness. I settled with the California Board of Registered Nursing (BRN) since my attorney felt it was better to have a reproval and fine versus going to trial with the BRN. I am not associated with that group, took the remedial courses for best clinical and prescribing practices. There are no restrictions on my license and I continue to practice with another group in California. This is my first personal interaction with the legal system and has been a very difficult situation to overcome. I currently contract with the MOST team in Lyon County, Reno Justice Court and Reno Municipal Court in Northern Nevada with their confidence in my quality of care. Due to this experience, I am more cautious with who I contract with but continue to serve the underprivileged and underinsured as that has always been my passion.

Please let me know if you have any other questions or need further information regarding this matter.

Document Name	Document Type	Date	Link	Action
Reproval Letter	Legal - Question 3	11/07/2024	Document Details	

Document Name : Document Type : Legal - Question 3

Document : Drop file here to upload or click here to browse and select file(s) to upload.

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Board Administrative Action :

State : Select Date : 04/28/2023

Case # : 4002020004350

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ○ Yes ◉ No

DEA Registration

Please upload a copy of your current DEA Registration associated with the Controlled Substance Registration you are renewing.

Document Name	Document Type	Date	Link	Action
Nevada DEA Registration.Exp10312025	NV DEA Certificate	11/07/2024	Document Details	

Document Name : Document Type : NV DEA Certificate

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload | Cancel

Acknowledgement and Declaration

☑ I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

By signing and submitting this renewal application, I certify that: 1. I hold an active and current Nevada license with my professional licensing board, and 2. My DEA certificate is CURRENT and reflects my current NV practicing address.

Signature : Steven Huerta

Date Of Application : 11/07/2024

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2024 to 10/31/2026	License Renewal Fee	$200.00
	Convenience Fee	$15.00
	Late Fee	$100.00
	Total :	**$315.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 15

Late Fees : 100

Reference Number : 120739547596

InvoiceDate : 11/07/2024

Paid

Pay & Submit

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **STEVEN THOMAS HUERTA** **Registered Nurse License No. 743486** **Nurse Practitioner Certificate No. 95003401** **Nurse Practitioner Furnishing Certificate No. 95003401** Respondent.	Case No. 4002020004350

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Registered Nursing, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on **April 28, 2023.**

IT IS SO ORDERED **March 29, 2023.**

Dolores Trujillo

Dolores Trujillo, RN
Board President
Board of Registered Nursing
Department of Consumer Affairs
State of California

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
DIANE DE KERVOR
Deputy Attorney General
State Bar No. 174721
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9415
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **STEVEN THOMAS HUERTA** [redacted] **Placentia, CA** [redacted] **Registered Nurse License No. 743486** **Nurse Practitioner Certificate No. 95003401** **Nurse Practitioner Furnishing Certificate No. 95003401** Respondent.	Case No. 4002020004350 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) is the Executive Officer of the Board of Registered Nursing (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Diane de Kervor, Deputy Attorney General.

2. Respondent Steven Thomas Huerta (Respondent) is represented in this proceeding by attorney Derek F. O'Reilly-Jones, Esq., whose address is: 355 South Grand Ave., Ste. 1750, Los Angeles, CA 90071-1562.

JURISDICTION

3. On or about January 29, 2009, the Board issued Registered Nurse License No. 743486 to Steven Thomas Huerta (Respondent). The Registered Nurse License was in full force and effect at all times relevant to the charges brought in Accusation No. 4002020004350 and will expire on March 31, 2024, unless renewed.

4. On or about November 4, 2015, the Board issued Nurse Practitioner Certificate No. 95003401 to Respondent. The Nurse Practitioner Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 4002020004350, and will expire on March 31, 2024, unless renewed.

5. On or about January 7, 2016, the Board issued Nurse Practitioner Furnishing Certificate No. 95003401 to Respondent. The Nurse Practitioner Furnishing Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 4002020004350, and will expire on March 31, 2024, unless renewed.

6. Accusation No. 4002020004350 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on July 29, 2022. Respondent timely filed his Notice of Defense contesting the Accusation.

7. A copy of Accusation No. 4002020004350 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4002020004350. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

11. Respondent understands and agrees that the charges and allegations in Accusation No. 4002020004350, if proven at a hearing, constitute cause for imposing discipline upon his Registered Nurse License, his Nurse Practitioner Certificate, and his Nurse Practitioner Furnishing Certificate.

12. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.

13. Respondent agrees that his Registered Nurse License, Nurse Practitioner Certificate and Nurse Practitioner Furnishing Certificate are subject to discipline and he agrees to be bound by the Disciplinary Order below.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board of Registered Nursing. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Registered Nursing may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary

Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

16. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

17. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Registered Nurse License No. 743486, Nurse Practitioner Certificate No. 95003401, and Nurse Practitioner Furnishing Certificate No. 95003401, issued to Respondent Steven Thomas Huerta (Respondent) shall be publicly reproved by the Board of Registered Nursing under Business and Professions Code section 495 in resolution of Accusation No. 4002020004350, attached as exhibit A.

Coursework. No later than six months from the effective date of the public reproval, Respondent, at his own expense, shall enroll, successfully complete and submit verification of course(s) relevant to the practice of registered nursing as specified by the Board. Respondent shall obtain prior approval from the Board before enrolling in the course(s). Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s).

Cost Recovery. Respondent shall pay $17,504.60 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew his Registered Nurse License, Nurse Practitioner Certificate, and Nurse Practitioner Furnishing Certificate until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 4002020004350, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Registered Nurse License No. 743486, Nurse Practitioner Certificate No. 95003401, and Nurse Practitioner Furnishing Certificate No. 95003401.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek F. O'Reilly-Jones, Esq. I understand the stipulation and the effect it will have on my Registered Nurse License, Nurse Practitioner Certificate, and Nurse Practitioner Furnishing Certificate. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Registered Nursing.

DATED: 12/20/2022

STEVEN THOMAS HUERTA
Respondent

I have read and fully discussed with Respondent Steven Thomas Huerta the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12.20.2022

Derek O'Reilly-Jones

DEREK F. O'REILLY-JONES, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Registered Nursing of the Department of Consumer Affairs.

DATED: December 21, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General

DIANE DE KERVOR
Deputy Attorney General
Attorneys for Complainant

SD2021801635
83728686

Exhibit A

Accusation No. 4002020004350

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Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **STEVEN THOMAS HUERTA** [redacted] **Placentia, CA 92870** **Registered Nurse License No. 743486** **Nurse Practitioner Certificate No. 95003401** **Nurse Practitioner Furnishing Certificate No. 95003401** Respondent.	Case No. 4002020004350 **ACCUSATION**

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing, Department of Consumer Affairs.

2. On or about January 29, 2009, the Board of Registered Nursing issued Registered Nurse License Number 743486 to Steven Thomas Huerta (Respondent). The Registered Nurse License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2024, unless renewed.

3. On or about November 4, 2015, the Board of Registered Nursing issued Nurse Practitioner Certificate Number 95003401 to Steven Thomas Huerta (Respondent). The Nurse Practitioner Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2024, unless renewed.

4. On or about January 7, 2016, the Board of Registered Nursing issued Nurse Practitioner Furnishing Certificate Number 95003401 to Steven Thomas Huerta (Respondent). The Nurse Practitioner Furnishing Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2024, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 2750 of the Code provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with section 2750) of the Nursing Practice Act.

7. Code section 2764 provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license.

STATUTORY PROVISIONS

8. Section 2761 of the Code states, in pertinent part:

> The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:
>
> (a) Unprofessional conduct, which includes, but is not limited to, the following:
>
> (1) Incompetence, or gross negligence in carrying out usual certified or licensed nursing functions.
>
> . . .
>
> (d)Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any provision or term of this chapter or regulations adopted pursuant to it....

9. Code section 2725 states:

. . . .

(b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

(1) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

(3) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.

(4) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures.

(c) "Standardized procedures," as used in this section, means either of the following:

(1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses.

(2) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

10. Code section 2725.1 states:

Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a licensed clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of the Health and Safety Code.

No clinic shall employ a registered nurse to perform dispensing duties

exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

11. Code section 2836.1 states, in pertinent part:

Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f)(1) Drugs or devices furnished or ordered by a nurse practitioner may

include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g)(1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed (1) at least six month's physician and surgeon-supervised experience in the furnishing or ordering of drugs or devices and (2) a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled substances based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

12. Code section 2836.2 states, in pertinent part:

Furnishing or ordering of drugs or devices by nurse practitioners is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure.

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REGULATORY PROVISIONS

13. California Code of Regulations (CCR), title 16, section 1442, states:

As used in Section 2761 of the code, "gross negligence" includes an extreme departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent registered nurse. Such an extreme departure means the repeated failure to provide nursing care as required or failure to provide care or to exercise ordinary precaution in a single situation which the nurse knew, or should have known, could have jeopardized the client's health or life.

14. CCR, title 16, section 1443, states:

As used in Section 2761 of the code, "incompetence" means the lack of possession of or the failure to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by a competent registered nurse as described in Section 1443.5.

15. CCR, title 16, section 1443.5, states:

A registered nurse shall be considered to be competent when he/she consistently demonstrates the ability to transfer scientific knowledge from social, biological and physical sciences in applying the nursing process, as follows:

(1) Formulates a nursing diagnosis through observation of the client's physical condition and behavior, and through interpretation of information obtained from the client and others, including the health team.

(2) Formulates a care plan, in collaboration with the client, which ensures that direct and indirect nursing care services provide for the client's safety, comfort, hygiene, and protection, and for disease prevention and restorative measures.

(3) Performs skills essential to the kind of nursing action to be taken, explains the health treatment to the client and family and teaches the client and family how to care for the client's health needs.

(4) Delegates tasks to subordinates based on the legal scopes of practice of the subordinates and on the preparation and capability needed in the tasks to be delegated, and effectively supervises nursing care being given by subordinates.

(5) Evaluates the effectiveness of the care plan through observation of the client's physical condition and behavior, signs and symptoms of illness, and reactions to treatment and through communication with the client and health team members, and modifies the plan as needed.

(6) Acts as the client's advocate, as circumstances require, by initiating action to improve health care or to change decisions or activities which are against the interests or wishes of the client, and by giving the client the opportunity to make informed decisions about health care before it is provided.

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16. CCR, title 16, section 1470, states:

The Board of Registered Nursing in conjunction with the Medical Board of California (see the regulations of the Medical Board of California, Article 9.5, Chapter 13, Title 16 of the California Code of Regulations) intends, by adopting the regulations contained in the article, to jointly promulgate guidelines for the development of standardized procedures to be used in organized health care systems which are subject to this rule. The purpose of these guidelines is:

(a) To protect consumers by providing evidence that the nurse meets all requirements to practice safely.

(b) To provide uniformity in development of standardized procedures.

17. CCR, title 16, section 1472, states:

An organized health care system must develop standardized procedures before permitting registered nurses to perform standardized procedure functions. A registered nurse may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedures; and must provide the system with satisfactory evidence that the nurse meets its experience, training, and/or education requirements to perform such functions.

18. CCR, title 16, section 1474, states:

Following are the standardized procedure guidelines jointly promulgated by the Medical Board of California and by the Board of Registered Nursing:

(a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.

(b) Each standardized procedure shall:

(1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.

(2) Specify which standardized procedure functions registered nurses may perform and under what circumstances.

(3) State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.

(4) Specify any experience, training, and/or education requirements for performance of standardized procedure functions.

(5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.

(6) Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.

(7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.

(8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.

(9) State the limitations on settings, if any, in which standardized procedure functions may be performed.

(10) Specify patient record keeping requirements.

(11) Provide for a method of periodic review of the standardized procedures.

COST RECOVERY

19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DEFINITIONS

20. Xanax is the brand name for alprazolam, a drug that is used to treat conditions such as anxiety and panic disorders. It belongs to a class of medications called benzodiazepines, which act on the nerves in the brain to produce a calming effect. Xanax can be highly addictive, and is typically recommended for short-term use only. With longer-term use, it usually leads to dependency and rebound anxiety. Xanax is a Schedule IV controlled substance.

21. Klonopin is the brand name for clonazepam, another benzodiazepine, which works similarly to Xanax but has a longer half-life. Klonopin also works by calming brain activity to help users feel relaxed. Although Klonopin also causes dependency, it has a longer half-life, which makes it more stabilizing with less withdrawal. Klonopin is a Schedule IV controlled substance.

FACTUAL ALLEGATIONS

22. In December of 2019, the Board received a complaint following a Department of Health Care Services (DHCS) audit of Mission City Community Network (MCCN) and several of its practitioners. MCCN is a clinic in the Los Angeles area that provides healthcare to the

uninsured and underprivileged population of Southern California, including homeless individuals and those recently released from incarceration.

23. From 2017 to 2020, Respondent was employed at MCCN as a telehealth Nurse Practitioner. Respondent worked under the supervision of Dr. VS.[1] Respondent reported that most of the patients that he saw were existing patients who had been initially evaluated by other providers. For the records reviewed, Respondent was only one of the providers for these patients, and his notes were all follow ups.

24. As a Nurse Practitioner, Respondent is licensed to examine, treat, and prescribe medications pursuant to standardized protocols. Neither Respondent, his supervising doctor, nor the facility could locate any standardized protocols for Respondent's practice at MCCN. His credential file included a California Participating Physician application, attestation to competencies, a Physician Extender agreement, other credentialing documentation, and a "Delegation of Services Agreement between Supervising Physician and Non-Physician Medical Practitioner." This agreement broadly permitted the named NP to perform "general medical" and psychiatric treatment and medication management, and to write and sign drug orders for schedule II, III, IV, and V medications with a listed DEA number. The agreement further directed the NP to seek consultation in cases of the "patient's failure to respond to therapy, nurse practitioner's uncertainty of diagnosis, patient's desire to see physician, any condition which the nurse practitioner feels exceeds his/her ability to manage, etc." These documents did not meet the statutory requirements for standardized protocols. No other standardized procedures or protocols setting forth the scope of Respondent's practice as a Nurse Practitioner were present in Respondent's employment or credential file, nor were they maintained by the doctor, respondent, or the employer. The collaborative agreement in the personnel file was not signed by the collaborating physician.

25. As a condition of his employment, Respondent was required to operate pursuant to MCCN's Gradual Dosage Reduction policy, which pertains to the recommended use and dosage

[1] As a result of the DHCS proceeding, and pursuant to Welfare and Institutions Code Section 14044, Dr. VS was placed on the Medi-Cal Procedure/Drug Code Limitation List. His limitation related to the prescribing of all psychotherapeutic drugs and benzodiazepines from January 6, 2021 to July 5, 2022.

of benzodiazepines, and which was implemented in 2018. The policy states, in pertinent part: "the long term risks of dependency and other cognitive decline may be greater than benefit," and "[s]witching from a short acting (Xanax) benzodiazepine to a long acting benzodiazepine (Klonopin) is a useful first step." The policy further states that providers should "attempt to decrease frequency and dosage for long term users versus discontinuation," advice for weekly tapering was provided,[2] and the policy provided that all patients being prescribed benzodiazepines are required to engage in psychotherapy at least once a month in order to develop healthy behaviors for coping with anxiety.

26. Overall, Respondent's treatment notes were mostly checklists, repeated the same statements for every patient, and incomplete or absent mental status checks. Problems were identified such as anxiety, insomnia, irritability but no new interventions were identified. No AIMS or medication side effect review was provided for those patients treated with antipsychotics. No CURES check was documented in the notes reviewed. The rationale for the medications prescribed was not described.

27. Respondent prescribed or continued the prescription of Xanax to all of the reviewed patients, usually at a dosage of 2 mg, and the prescriptions lasted for years. Respondent failed to provide documentation justifying the medical necessity of these lengthy Xanax prescriptions that he refilled. Contrary to MCCN's Gradual Dosage Policy, Respondent did not document attempts to taper patients off of short-term benzodiazepines. Xanax was prescribed with no risk, benefit review or suggestion of lowering the medication or documentation of discussing an alternative medication for anxiety.

28. According to the MCCN patient records reviewed, Respondent prescribed or continued prescriptions for Xanax as follows:

Patient	Date Issued	Strength	Quantity	Frequency	Diagnosis
W	11/8/2017	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type

[2] "Reduce the total daily dose by 5-10% per week in divided doses. Note that for long- term uses, the goal is reduction in frequency and dose versus discontinuation. … Once 1/2 of the original dose has been reached, the taper can be slowed further by decreasing the dose each month thereafter."

W	1/8/2018	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
W	2/5/2018	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
W	3/7/2018	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
W	4/4/2018	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
E	10/2/2017	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
E	11/13/2017	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
E	5/30/2018	2 mg	½ tab	Twice a day PRN Anxiety	Schizoaffective Disorder, Depressive Type
M	8/7/2017	2 mg	½ tab	Twice a day	Anxiety Disorder; Major Depressive Disorder
M	3/5/2018	2 mg	½ tab	Twice a day	Anxiety Disorder; Major Depressive Disorder
M	4/4/2018	2 mg	½ tab	Twice a day	Anxiety Disorder; Major Depressive Disorder
M	5/2/2018	2 mg	½ tab	Twice a day	Anxiety Disorder; Major Depressive Disorder
B	8/2/2017	2 mg	½ tab	Twice a day	Generalized Anxiety Disorder
B	12/11/17	1 mg	½ tab	Twice a day Prn anxiety	Generalized Anxiety Disorder
B	3/19/2018	2 mg	½ tab	Twice a day Prn anxiety	Generalized Anxiety Disorder
B	5/21/2018	2 mg	½ tab	Twice a day Prn anxiety	Generalized Anxiety Disorder

29. The standard of practice for a psychiatric nurse practitioner requires assessment (using evidence-based principles, knowledge, and clinical expertise), diagnosis, implementation of a treatment plan (appropriate/safe/evidence-based pharmacologic interventions, health teaching, health promotion and consultation), and ongoing evaluation.

30. Respondent's patient records departed from the standard of practice in several ways. Because he was not operating under standardized protocols, Respondent was acting outside the scope of his licensure when treating these patients. Of the medical records reviewed, the documentation was minimal and Respondent did not address concerning symptoms. The mental status exams were not complete and the rationale/justification for prescribed medications was not defined and at times not appropriate. Some pharmacologic interventions were not evidence based

or provided justification.[3] Overall, the treatment plans were lacking in health teaching, health promotion and treatment goals for recovery. Patients did not receive the expected level of care provided by a skilled and knowledgeable Nurse Practitioner.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

31. Respondent is subject to disciplinary action under Code section 2761, subdivision (a)(1), for gross negligence as defined by California Code of Regulations, title 16, section 1442, in that he repeatedly failed to meet the standard of practice for a competent nurse practitioner, as more fully set forth in paragraphs 22-30 and incorporated by this reference as though set forth in full. Respondent repeatedly failed to follow the standard of practice as he did not document/provide comprehensive evidence-based assessment, treatment, standard of care medication management to his patients that a competent Nurse Practitioner would have provided.

SECOND CAUSE FOR DISCIPLINE

(Incompetence)

32. Respondent is subject to disciplinary action under Code section 2761, subdivision (a)(1), for incompetence as defined by CCR, title 16, section 1443, in that Respondent failed to exercise the degree of learning, skill, care, and experience ordinarily possessed and exercised by a competent nurse practitioner, as more fully set forth in paragraphs 22-31 and incorporated by this reference as though set forth in full.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

33. Respondent is subject to disciplinary action under Code sections 2761, subdivisions (a) and (d), 2725, and 2836.1, as well as Regulation section 1472 and 1474 for unprofessional conduct, as more fully set forth in paragraphs 22-32, and as follows:

a. Respondent failed to provide comprehensive evidence-based assessment, treatment, medication management, and/or provide thorough documentation of such.

[3] Although not FDA approved, Respondent continued the prescription of Abilify as the only agent of treatment after a diagnosis of Generalized Anxiety Disorder and Major Depression for Patient MF.

b. The documents in Respondent's employment and credential file do not qualify as standardized protocols.

c. Respondent was not practicing and prescribing pursuant to required standardized protocols, which specify what drugs may be prescribed and under what circumstances.

d. Respondent did not follow facility practices or procedures in the treatment of his patients, including implementation of the facility's Gradual Dosage Reduction policy.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violation of Laws)

34. Respondent is subject to disciplinary action under section 2761(d) for unprofessional conduct in that Respondent violated or attempted to violate, directly or indirectly, the provisions or terms of the Nurse Practice Act, specifically Code sections 2725.1, 2836.1, and 2836.2, and Regulation sections 1472 and 1474, when he prescribed or furnished controlled substances to patients without standardized procedures and protocols for nurse practitioners, as more fully set forth in paragraphs 22-33 and incorporated by this reference as though set forth in full.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 743486, issued to Steven Thomas Huerta;

2. Revoking or suspending Nurse Practitioner Certificate Number 95003401, issued to Steven Thomas Huerta

3. Revoking or suspending Nurse Practitioner Furnishing Certificate Number 95003401, issued to Steven Thomas Huerta;

4. Ordering Steven Thomas Huerta to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

5. Taking such other and further action as deemed necessary and proper.

DATED: July 22, 2022

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

SD2021801635; 83349377

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NRS 639.120 Qualifications of applicants to become registered pharmacists.

1. Except as otherwise provided in NRS 639.134, 639.136 and 639.1365, an applicant to become a registered pharmacist in this State must:

(a) Be of good moral character.

(b) Be a graduate of a college of pharmacy or department of pharmacy of a university accredited by the Accreditation Council for Pharmacy Education or Canadian Council for Accreditation of Pharmacy Programs and approved by the Board or a graduate of a foreign school who has passed an examination for foreign graduates approved by the Board to demonstrate that his or her education is equivalent.

(c) Except as otherwise provided in NRS 622.090:

(1) Pass an examination approved and given by the Board with a grade of at least 75 on the examination as a whole and a grade of at least 75 on the examination on law.

(2) If he or she is an applicant for registration by reciprocity, pass the examination on law with at least a grade of 75.

(d) Complete not less than 1,500 hours of practical pharmaceutical experience as an intern pharmacist under the direct and immediate supervision of a registered pharmacist.

2. The practical pharmaceutical experience required pursuant to paragraph (d) of subsection 1 must relate primarily to the selling of drugs, poisons and devices, the compounding and dispensing of prescriptions, preparing prescriptions and keeping records and preparing reports required by state and federal statutes.

3. The Board may accept evidence of compliance with the requirements set forth in paragraph (d) of subsection 1 from boards of pharmacy of other states in which the experience requirement is equivalent to the requirements in this State.

16

16A

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R113-24

July 15, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§ 1 and 2, NRS 639.070; §§ 3-5, NRS 639.070 and 639.1371.

A REGULATION relating to pharmacy; establishing requirements governing the staffing of certain pharmacies; revising provisions concerning the supervision of pharmaceutical technicians and pharmaceutical technicians in training; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the practice of pharmacy in this State. (NRS 639.070) **Sections 2 and 3** of this regulation establish requirements governing the minimum number of pharmacists and pharmaceutical technicians or pharmaceutical technicians in training, respectively, who must be working in a pharmacy that dispenses controlled substances or dangerous drugs, with certain exceptions. **Section 4** of this regulation additionally requires a pharmacy that dispenses controlled substances or dangerous drugs to: (1) be staffed in a manner that meets the demands of the pharmacy and prioritizes patient care and safety; and (2) maintain records of the hours worked by pharmacists, pharmaceutical technicians and pharmaceutical technicians in training. **Section 4** also requires the managing pharmacist of such a pharmacy to ensure that the pharmacy complies with the requirements of **sections 2-4**. **Section 4** additionally requires a pharmacist who is on the staff of a pharmacy that is subject to the requirements of **sections 2 and 3** to notify the Board when the pharmacy is out of compliance with those requirements for at least 3 days.

Existing law requires the Board to adopt regulations concerning pharmaceutical technicians, including requirements for the supervision of pharmaceutical technicians. (NRS 639.1371) **Section 5** of this regulation revises the number of pharmaceutical technicians or pharmaceutical technicians in training that a pharmacist is authorized to supervise, depending on the type of pharmacy in which the pharmacist is working. **Section 5** also removes authorization for a pharmacist working in certain pharmacies to exceed the number of pharmaceutical technicians he or she would otherwise be authorized to supervise under certain circumstances. **Sections 4 and 5**, respectively, require a pharmacist who is on the staff of a pharmacy to report to the Board concerning: (1) a failure of the pharmacy to comply with the requirements of **section 2 or 3** for any period over 3 consecutive days; or (2) any failure of the pharmacy to comply with requirements governing the supervision of pharmaceutical technicians.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

Sec. 2. ***1. Except as otherwise provided in subsection 2, a pharmacy that dispenses controlled substances or dangerous drugs, other than an institutional pharmacy or a pharmacy in a correctional institution, must have not less than:***

(a) One pharmacist working during the entirety of each hour the pharmacy fills less than 20 prescriptions.

(b) Two pharmacists working during the entirety of each hour the pharmacy fills at least 20 prescriptions, plus at least one additional pharmacist working during the entirety of such an hour for each additional 20 prescriptions the pharmacy fills during that hour.

(c) In addition to the requirements of paragraph (a) or (b), as applicable, one pharmacist working during the entirety of each hour that the pharmacy provides both nondispensing services and dispensing services. A pharmacist described in this paragraph must be designated to provide nondispensing services, but may assist in providing dispensing services, including the dispensing of controlled substances or dangerous drugs, if, in the professional judgment of the pharmacist, patient care and safety are not compromised.

2. The requirements of paragraph (c) of subsection 1 do not apply to a pharmacy that fills less than 10 prescriptions per hour.

3. As used in this section:

(a) "Dispensing services" means the filling and dispensing of prescriptions.

(b) "Nondispensing services" means all activities that a pharmacist performs except for dispensing services.

Sec. 3. ***Except as otherwise provided in NAC 639.250, a pharmacy that dispenses controlled substances or dangerous drugs, other than an institutional pharmacy or a pharmacy in a correctional institution, must have not less than:***

1. One pharmaceutical technician or pharmaceutical technician in training working during the entirety of each hour the pharmacy fills at least five but not more than nine prescriptions.

2. Two pharmaceutical technicians or pharmaceutical technicians in training working during the entirety of each hour the pharmacy fills at least 10 but not more than 19 prescriptions.

3. Three pharmaceutical technicians or pharmaceutical technicians in training working during the entirety of each hour the pharmacy fills at least 20 prescriptions, plus one additional pharmaceutical technician or pharmaceutical technician in training working during the entirety of such an hour for each additional 20 prescriptions the pharmacy fills during that hour.

Sec. 4. ***1. A pharmacy that dispenses controlled substances or dangerous drugs must be staffed in a manner that meets the demands of the pharmacy and prioritizes patient care and safety.***

2. The names and hours worked of each pharmacist, pharmaceutical technician and pharmaceutical technician in training must be documented in the records of a pharmacy that dispenses controlled substances or dangerous drugs. The pharmacy shall maintain such records in an easily retrievable manner for at least 2 years after the hours worked to which the records apply.

3. The managing pharmacist of a pharmacy that dispenses controlled substances or dangerous drugs shall ensure that the pharmacy complies with sections 2, 3 and 4 of this regulation, to the extent applicable.

4. A pharmacist who is on the staff of a pharmacy that dispenses controlled substances or dangerous drugs, other than an institutional pharmacy or a pharmacy in a correctional institution, including, without limitation, the managing pharmacist of such a pharmacy, shall report to the Board when the pharmacy fails to meet the requirements of section 2 or 3 of this regulation for any period of time during each of 3 consecutive days.

Sec. 5. NAC 639.250 is hereby amended to read as follows:

639.250 Except as otherwise provided in NAC 639.258:

1. Except as otherwise provided in subsection 5, in ~~[a hospital,]~~ ***an institutional pharmacy or a pharmacy in a correctional institution,*** a pharmacist who is dispensing prescriptions may not supervise more than a total of three pharmaceutical technicians at one time. A pharmacist who is supervising distributive functions may not supervise more than a total of two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.

2. ~~[Except as otherwise provided in subsection 5, in]~~ ***In*** any pharmacy, other than ~~[a hospital]~~ ***an institutional*** pharmacy, ***pharmacy in a correctional institution,*** telepharmacy, remote site, satellite consultation site or nondispensing pharmacy, a pharmacist may not supervise more than a total of ~~[three]~~ ***four*** pharmaceutical technicians or ~~[one]~~ ***two*** pharmaceutical ~~[technician]~~ ***technicians*** and two pharmaceutical technicians in training at one time.

3. In any telepharmacy, remote site or satellite consultation site, a pharmacist may not supervise more than a total of three pharmaceutical technicians at one time.

4. In any nondispensing pharmacy, a pharmacist may not supervise more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time.

5. A pharmacist ***in an institutional pharmacy or a pharmacy in a correctional institution*** may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to ~~[subsections]~~ ***subsection*** 1 ~~[and 2]~~ if:

(a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

(b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.

6. A pharmacist who is on the staff of a pharmacy, including, without limitation, the managing pharmacist of such a pharmacy, shall report to the Board when the pharmacy fails to meet the requirements of this section.

~~[6.]~~ ***7.*** As used in this section, "nondispensing pharmacy" means a pharmacy that is licensed pursuant to this chapter and chapter 639 of NRS that does not dispense, including, without limitation, drugs, controlled substances, poisons, medicines or chemicals.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB FILE NO. R113-24I

The following document is the initial draft regulation proposed by the agency submitted on 06/03/2024

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – May 29, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted. and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.1371

A REGULATION relating to pharmacy; minimum staffing requirements in the pharmacy; restriction on supervision; and providing other matters properly relating thereto.

The proposed regulation is a result of the Nevada Pharmacists Workplace and Patient Safety Survey. There were three main recuring themes that needs to be addressed based on the results of the survey:

1. The pharmacies need to eliminate workload productivity metrics.
2. The pharmacies need more staff, particularly pharmacists, but pharmaceutical technicians as well.
3. The pharmacies need to separate dispensing services from non-dispensing services.

This is supported by the results of the following survey questions:

7-*"To keep up with work related tasks, how often do you continue working after your scheduled/paid shift hours have been completed."* - The top answer amongst Retail Chain Pharmacists was "Always" and "Usually" (55%). While only 28% and 26% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answered, "Always" and "Usually," respectively.

16- *"Do you believe your primary practice setting is sufficiently staffed to meet the demands of the pharmacy while meeting patient care and safety standards?"* - The top answer amongst the Retail Chain Pharmacists and Institutional/Hospital Pharmacists was "No" (74.6% and 52.3%, respectively.)

17- *"Do you believe the current staffing in your primary practice setting poses a risk to patient safety?"* – The top answer amongst the Retail Chain Pharmacists was "Yes" (68.3%) while the top answer for Institutional/Hospital Pharmacists was "No" (51.7%).

18- *"If you could choose to add more staff to assist in the demands of your pharmacy to ensure patient care and safety is prioritized, which would you choose?"* – The top answer amongst all the pharmacists was "Additional Pharmacists."

19- *"I feel that my work environment has sufficient pharmacy technicians staffing that allows for safe patient care?"* - The top answer amongst Retail Chain Pharmacists were "Strongly disagree" or "Disagree" (63%). While only 38% and 18% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answered, "Strongly disagree" or "Disagree," respectively.

20- *"I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care."* - The top answer amongst Retail Chain Pharmacists was "Disagree." While the top answer amongst Institutional/Hospital Pharmacists and pharmacists in other practice settings was "Agree" or "Strongly Agree."

21- *"I feel that staffing at my pharmacy is adequate to prevent delays in patients receiving medications in a timely manner."* – The top answers amongst Retail Chain Pharmacists were "Strongly Disagree" and "Disagree."

28 – *"In your opinion, how does completing non-dispensing services affect your ability to dispense prescriptions effectively?"* - The top answer amongst Retail Chain Pharmacists were "It somewhat diminishes my ability to dispense prescriptions effectively" or "It greatly diminishes my ability to dispense prescriptions effectively" (83%). While only 27% and 22% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answered, "It somewhat diminishes my ability to dispense prescriptions effectively" or "It greatly diminishes my ability to dispense prescriptions effectively," respectively.

29- *"In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect your ability to practice safely?"* – The top answer amongst Retail Chain Pharmacists were "It somewhat diminishes my ability to practice safely" or "It greatly diminishes my ability to practice safely" (83%). While only 36% and 21% of Institutional/Hospital pharmacist and pharmacists in other practice settings answered, "It somewhat diminishes my ability to practice safely" or "It greatly diminishes my ability to practice safely," respectively.

30- "*In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect patient from getting their medications in a timely manner?"* - The top answer amongst the Retail Chain Pharmacists were "It greatly diminishes patients from getting their medications in a timely manner" or "It somewhat diminishes patients from getting their medications in a timely manner" (89%). While only 40% and 22% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answered, "It greatly diminishes patients from getting their medications in a timely manner" or "It somewhat diminishes patients from getting their medications in a timely manner," respectively.

32- *"Do you feel that you have been pressured by your employer or supervisor to meet standards or metrics that may interfere with safe patient care?"* - The top answers amongst the Retail Chain Pharmacists were "Yes" or "Somewhat" (86%). While only 37% and 19% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answer, "Yes" or "Somewhat," respectively.

38 – *"In your opinion, how would an increase in the number of pharmaceutical technicians (PT) and pharmaceutical technicians in training (PTT) you may supervise in your primary practice setting affect patient safety?* - The top answer amongst the Retail Chain Pharmacists was "Improve patient safety" (69%).

40- *"In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect patient safety?"* - The top answer amongst all pharmacists was "Improve patient safety."

45 – *"In your opinion, are you able to comfortably take meals and rest periods without feeling like you will fall behind or compromise patient care or safety."* – The top answer amongst the Retail Chain Pharmacists was "No" (70%). While only 42% and 23% of Institutional/Hospital Pharmacists and pharmacists in other practice settings answered, "No," respectively.

47- *"Please rank the following from 1 to 7 on their impact on patient safety (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety"* – The top 3 answers amongst all the pharmacists survey participants were 1) Eliminating workload productivity metrics, 2) Increasing the number of pharmacists staffed, and 3) Eliminating non-dispensing responsibility for pharmacists processing prescriptions.

48 – *"My current workload is:"* The top answer amongst Retail Chain Pharmacists were "High" or "Excessively High" (82%). While only 58% and 24% of Institutional/Hospital Pharmacists or pharmacists in other practice settings answered, "High" or "Excessively High, "respectively.

54- *"In your opinion, what is the number of prescriptions ONE pharmacist should be able to reasonably and safely fill on a given weekday, working from 9am to 7pm, in a general retail pharmacy setting, with the assistance of one to three pharmaceutical technicians or pharmaceutical technicians in training IF non-dispensing services such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education and quality improvement projects ARE EXCLUDED?"* - The top answer amongst all pharmacist survey participants was 101-200 prescriptions.

Free-fill responses for questions 55, 56, and 57- majority of the responses were

1. The pharmacies need to eliminate workload productivity metrics.
2. The pharmacies need more staff, particularly pharmacists, but pharmaceutical technicians as well.
3. The pharmacies need to separate dispensing services from non-dispensing services.

To address the above issues, minimum staffing standards should be required of retail community pharmacies. If the proposed regulation is adopted it will address items 2 and 3 of the survey. Addressing items 2 and 3 will address the issue regarding item 1, workload productivity metrics.

NAC Chapter 639 is hereby amended by adding thereto a new section to read as follows:

1. ***A pharmacy, as defined in NRS 639.012, except an institutional pharmacy, as defined by NRS 639.0085, and a pharmacy in a correctional institution, as defined by NRS 639.0123 engaged in the dispensing of controlled substances or dangerous drugs shall staff a pharmacy in a manner that meets the demand of the pharmacy while prioritizing patient care and safety.***

   a. ***The following are the minimum pharmacist staffing requirements:***

      i. ***A pharmacy shall staff the pharmacy with a minimum of two (2) pharmacists for every hour the pharmacy is filling greater than or equal to twenty (20) prescriptions per hour; (see survey results for questions 7, 16, 17, 18, 20, 21, 40, 45, 47, 48, 54, 55, 56, 57)***

      ii. ***The pharmacy shall add, at a minimum, an additional pharmacist for every twenty (20) prescriptions filled per hour thereafter by the pharmacy; and (see survey results for questions 7, 16, 17, 18, 20, 21, 40, 45, 47, 48, 54, 55, 56, 57)***

      iii. ***If the pharmacy is engaged in providing non-dispensing services during the hours the pharmacy is also providing dispensing services, the pharmacy must add an additional pharmacist designated to perform the non-dispensing services. (see survey results for questions 28, 29, 30, 40, 47, 55, 56, 57)***

         1. ***The pharmacist designated to perform the non-dispensing services may assist in the dispensing of controlled substances or dangerous drugs if in the professional judgement of the pharmacist time permits and patient care and safety is not compromised, but this pharmacist may not be used to meet the minimum requirements as specified in paragraphs i and ii of subsection (a) of this section.***
         2. ***Except as specified in subsection iv, a pharmacy must cease providing non-dispensing services if there is no pharmacist solely designated to perform the non-dispensing services.***

      iv. ***A pharmacist while engaged in the dispensing of controlled substances or dangerous drugs shall not engage in any non-dispensing services, except when the pharmacy is staffed with one pharmacist and the pharmacy is filling less than ten (10) prescriptions per hour.***

Example (Ex) 1: A pharmacy filling 10-19 RXs/h (~ 100-190 RXs in a 10h shift) will need **1 pharmacist** during those hours. A pharmacy providing non-dispensing services during the same hours will need **2 pharmacists**.

Ex 2: A pharmacy filling 20-39 RXs/h (~ 200-390 RXs in a 10hr shift) will need **2 pharmacists** during those hours. A pharmacy providing non-dispensing services during the same hours will need **3 pharmacists**.

Ex 3: A pharmacy filling 40-59 RXs/h (~ 400-590 RXs in a 10h shift) will need **3 pharmacists** during those hours. A pharmacy providing non-dispensing services during the same hours will need **4 pharmacists**, etc.

Ex 4: A pharmacy filling 0-9 RXs/h (~ 0-90 RXs in a 10h shift) will need **1 pharmacist** during those hours. The same pharmacist may provide non-dispensing services during the same hours.

DRAFT

b. Except as otherwise provided in NAC 639.250, the following are the minimum pharmaceutical technician and pharmaceutical technician in training staffing requirements: (see survey results for questions 16, 19, 21, 38, 55, 56, 57)

i. A pharmacy shall staff the pharmacy with a minimum of one (1) pharmaceutical technician or pharmaceutical technician in training for every hour the pharmacy is filling greater than five (5) but less than ten (10) prescriptions per hour;

Ex 1: A pharmacy filling 5-9 RXs/h (~ 50-90 RXs in a 10h shift) will need **1 PT or PTT** during those hours.

ii. A pharmacy shall staff the pharmacy with a minimum of two (2) pharmaceutical technician or pharmaceutical technician in training for every hour the pharmacy is filling greater than or equal to ten (10) prescriptions but less than twenty (20) prescriptions per hour;

Ex 2: A pharmacy filling 10-19 RXs/h (~ 100-190 RXs in a 10h shift) will need **2 PTs or PTT**s during those hours.

iii. A pharmacy shall staff the pharmacy with a minimum of three (3) pharmaceutical technicians or pharmaceutical technicians in training for every hour the pharmacy is filling greater than or equal to twenty (20) prescriptions per hour; and

Ex 3: A pharmacy filling 20-39 RXs/h (~ 200-390 RXs in a 10h shift) will need **3 PTs or PTTs** during those hours.

iv. The pharmacy shall add, at a minimum, an additional pharmaceutical technician or pharmaceutical technician for every twenty (20) prescriptions filled per hour thereafter by the pharmacy.

Ex 4: A pharmacy filling 40-59 RXs/h (~ 400-590 RXs in a 10h shift) will need **4 PTs or PTTs** during those hours, etc.

2. The managing pharmacist has the duty to enforce the provisions in these sections and maintain documentation of hourly compliance with these sections, including, but not limited the name of the pharmacist, and the name of the pharmaceutical technician or pharmaceutical technician staffed each hour and day, and is responsible for ensuring there is documentation of each hour and day the pharmacy fails to maintain minimum staffing requirements. This document must be readily retrievable and maintained for at least 2 years.

3. The pharmacy, managing pharmacist, and all registered pharmacists have the duty to report to the Board when the pharmacy fails to maintain minimum staffing requirements for any hours during three (3) consecutive days.

4. As used in this section "non-dispensing services" means all activities that a registered pharmacist may perform except for the filling, dispensing, and counseling of prescriptions.

DRAFT

NAC 639.250 is amended to read as follows ***(see survey results for questions 16, 19, 21, 38, 55, 56, 57)*****:**

NAC 639.250 Restrictions on supervision. (NRS 639.070**,** 639.0727**,** 639.1371**)** Except as otherwise provided in NAC 639.258:

1. Except as otherwise provided in subsection 5, in a***n*** ~~[hospital]~~ ***institutional pharmacy or a pharmacy in a correctional institution***, a pharmacist who is dispensing prescriptions may not supervise more than a total of three pharmaceutical technician at one time. A pharmacist who is supervising distributive functions may not supervise more than a total of two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.

2. ~~[Except as otherwise provided in subsection 5,]~~ ~~[i]~~***I***n any pharmacy, other than a***n*** ~~[hospital]~~ ***institutional*** pharmacy, ***a pharmacy in a correctional institution,*** telepharmacy, remote site, satellite consultation site or nondispensing pharmacy, a pharmacist may not supervise more than a total of ~~[three]~~ ***four*** pharmaceutical technicians or ~~**[one]**~~ ***two*** pharmaceutical technician and two pharmaceutical technicians in training at one time.

3. In any telepharmacy, remote site or satellite consultation site, a pharmacist may not supervise more than a total of three pharmaceutical technicians at one time.

4. In any nondispensing pharmacy, a pharmacist may not supervise more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time.

5. A pharmacist may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to subsections 1 and 2 if:

(a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

(b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.]

6. As used in this section, "nondispensing pharmacy" means a pharmacy that is licensed pursuant to this chapter and chapter 639 of NRS that does not dispense, including, without limitation, drugs, controlled substances, poisons, medicines or chemicals.

7. The pharmacy, managing pharmacist, and all registered pharmacists have the duty to immediately report to the Board when the pharmacy exceeds restriction on supervision.

DRAFT

From:	Scott Young
To:	Board Coordination
Subject:	Staff Requirements R113-24RPI Comments
Date:	Wednesday, October 23, 2024 4:42:41 PM
Attachments:	Nevada Staffing Requirements R113-24RP1 Comments.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Nevada State Board of Pharmacy,

Good evening. Attached are comments regarding the proposed staffing requirements, R113-24RPI. We have heard some adjustments are being made, but we felt this language was significant enough that we needed to reiterate our concerns. We feel the proposed language needs to be revised to accommodate closed-door pharmacies or we strongly recommend that the Board provide a waiver process for closed-door pharmacies. If there are revisions that the Board can share, we would greatly appreciate seeing them. Thank you very much.

Scott Young
VP, Legislative & Regulatory Affairs
Senior Policy Specialist, Pharmacy & Pharmaceutical Policy
Animal Policy Group (APG)

Animal Policy Group

October 22, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Ste. 206
Reno, Nevada 89521

Board of Pharmacy,

We submitted comments for the May hearing on R113-24, but these rules are significant enough that we feel it is necessary to reiterate our concerns.

The pharmacy community is extremely diverse. R113-24 may try to address this by proposing different staff ratios based on the number of prescriptions processed, but it fails to take into consideration other factors. In fact, we would argue that these other factors are more important in determining ratios than prescription metrics.

Closed-door pharmacies can process more prescriptions than public-facing pharmacies without compromising public safety. They have fewer distractions and can separate and automate functions in ways public-facing pharmacies cannot. A lot of states recognize this and provide significant flexibility for closed-door pharmacies. Since the May hearing, California agreed to allow a higher ratio for closed-door pharmacies and Florida increased their ratio for closed-door pharmacies to 12:1.

It is not uncommon for a closed-door pharmacy to fill more than 65 prescriptions per hour. Under R113-24, a pharmacy would be required to have on staff at least four pharmacists and five pharmacy techs or techs-in-training, a 5:4 ratio. This is unreasonable for closed-door pharmacies, and the staffing costs are unsustainable for most pharmacies. We cannot stress this enough. We are concerned this proposal will force closed-door pharmacies to make difficult decisions regarding their ability to operate under these conditions. We do not feel that is best for the state or the closed-door pharmacy community.

There are other factors that should be taken into consideration, as well, such as whether a pharmacy compounds, carries controlled substances, or serves a specialized audience (like animals).

We encourage the Board to bring this proposal back for further discussion and work with stakeholders on language that would better accommodate the diversity of pharmacies. At a minimum, we strongly encourage the Board to adopt a waiver process to allow pharmacies the opportunity to make a case for additional flexibility based on their specific situation. We welcome any opportunity to further discuss this with the Board and participate in any revisions.

Sincerely,

Scott Young
Senior Director, Pharmacy and Pharmaceutical Policy
scott@animalpolicygroup.com

From: Joseph Montemorano
To: Board Coordination
Subject: Subject: Support for Proposal R-113-24 - Pharmacist Workload and Patient Safety
Date: Friday, October 11, 2024 6:32:11 AM

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Nevada Board of Pharmacy,
As a pharmacist with 40 years of experience in chain retail pharmacy, I am writing to express **my strong support for proposal R-113-24**. I am deeply grateful that the Board is taking action to address the critical issues of pharmacist workload and patient safety.
Here are seven key reasons why I believe this proposal is necessary and long overdue:

- **Patient Safety:** The high volume of dispensing and non-dispensing duties has created unsafe conditions, leaving insufficient time to properly research drug interactions, verify doses, and assess therapy appropriateness.
- **Consultation Quality:** The current workload makes providing effective patient consultation on all new prescriptions extremely challenging, which is crucial for medication adherence and safety.
- **Corporate Accountability:** This proposal addresses the root cause of many safety concerns in pharmacy practice by holding chain retail corporations accountable.
- **Unrealistic Metrics:** The key performance metrics imposed by corporations have become increasingly difficult to meet consistently, leading to undue stress and potential errors.
- **Pharmacist Burnout:** The relentless pressure to meet metrics while maintaining safety has contributed significantly to pharmacist burnout, affecting personal well-being and patient care quality.
- **Balancing Efficiency and Safety:** This proposal recognizes the need to balance corporate efficiency goals with the paramount concern of patient safety.
- **Professional Autonomy:** By limiting excessive workloads, this proposal helps restore professional autonomy to pharmacists, allowing us to exercise our clinical judgment more effectively.

I am thankful that the Board is taking these crucial steps to protect both patients and pharmacists. This action demonstrates a commitment to the core values of our profession and the health of our communities. (See references below)
Thank you for your consideration and leadership on this critical issue.

Sincerely,
Joseph Montemorano BSPham
Registered Pharmacist since 1983
Cell [redacted]
Email [redacted]

References

. Nevada Board of Pharmacy Proposal R-113-24 Document

. American Pharmacists Association (APhA) Guidelines on Patient Safety

. National Association of Boards of Pharmacy (NABP) Standards for Pharmacy Practice

. Journal of the American Pharmacists Association - Studies on Pharmacist Workload and Patient Safety

. Centers for Disease Control and Prevention (CDC) - Medication Safety Guidelines

Nevada Pharmacists Workplace and Patient Safety Survey

In 2023, patient safety as it relates to workplace conditions in licensed pharmacies grew to be a primary concern of the Nevada State Board of Pharmacy (Board).

To examine workplace factors and conditions that may be affecting accurate and timely pharmaceutical care, the Board created a 61-question survey known as the **Nevada Pharmacists Workplace and Patient Safety Survey**. The survey was distributed to 2,761 Nevada licensed pharmacists on November 17, 2023, and responses were collected through December 31, 2023. Responses to the survey were optional. Of the 2,761 surveys distributed, the Board received 945 responses. After removing responses not linked to a Nevada pharmacist license number and duplicated responses from the same licensee, 824 responses (30% of surveys distributed) were included in the results of this report.



Survey Questions

Nevada Pharmacists Workplace and Patient Safety Survey

ATTENTION PHARMACISTS

The Nevada State Board of Pharmacy (Board) is concerned about patient safety as it relates to workplace conditions in licensed pharmacies. We are seeking to better understand the safety concerns.

The Board is requesting that you complete the following survey. Your responses will allow the Board to examine workplace factors and conditions that may be affecting accurate and timely pharmaceutical care. Your response to this survey is extremely important and is completely anonymous. Only aggregated, non-identifiable data from the report will be made available to the public. Your responses can change the practice of pharmacy and will directly guide the Board in what new regulations will need to be promulgated to protect and improve patient care. The survey should only take a few minutes to complete. We appreciate your participation.

1. Provide your pharmacist license number. Your responses will not be calculated into the results of the survey if your license number is not provided. Your license number will be used strictly as a means of (1) limiting the population of survey participants to Nevada-registered pharmacists and (2) excluding duplicate surveys. It will not be used to correlate individual responses with an identifiable survey participant. _____

2. How many years have you been in the practice of pharmacy?
    a. 0-10 years
    b. 11-20 years
    c. 21-30 years
    d. 30+ years

3. Which of the following most closely describes your primary practice setting?
    a. Institutional/Hospital Pharmacy
    b. Retail Chain Pharmacy
    c. Independent Pharmacy
    d. Department of Defense or Veterans Affairs Pharmacy
    e. Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)
    f. Consultant Pharmacist
    g. None of the above. I am currently unemployed or retired.

4. Are you the owner of the pharmacy where you primarily practice?
    a. Yes
    b. No

5. What is your employment status?
    a. Full-time
    b. Part-time
    c. As needed (PRN)
    d. Unemployed
    e. Retired
    f. Not currently practicing due to my choice

6. How many hours per week do you work at your primary practice setting (please include paid and unpaid hours)?
    a. >60 hours
    b. 51-60 hours
    c. 41-50 hours
    d. 31-40 hours
    e. 20-30 hours
    f. <20 hours
    g. Not applicable

7. To keep up with work related tasks, how often do you continue working after your scheduled/paid shift hours have been completed?
    a. Always
    b. Usually
    c. Sometimes
    d. Rarely
    e. Never
    f. Not applicable

8. What is your role at your primary practice setting?
    a. Pharmacist-in-charge (PIC)
    b. Staff Pharmacist
    c. Consultant Pharmacist
    d. Floater
    e. Not applicable

9. If you are the designated PIC, do you feel you have sufficient autonomy and power to fulfill your duties as the PIC?
    a. Yes
    b. No
    c. Not applicable

10. How long is a typical work shift at your primary practice setting?
    a. < 8 hours
    b. 8 hours
    c. 10 hours
    d. 12 hours
    e. > 12 hours
    f. It varies
    g. Not applicable

11. Which of the following most closely describes the shift you work at your primary practice setting?
    a. First Shift (Begins and ends around 7-9 AM to 4-5 PM)
    b. Second Shift (Begins and ends around 11 AM to 7 PM or 3 PM to 10 PM)
    c. Third Shift (Begins and ends around 10 PM or 12 AM to 7-9 AM)
    d. Rotating shifts
    e. Not applicable

12. Provide the number of pharmacists that work during your shift?
    a. 1
    b. 2

c. 3
d. 4
e. 5
f. >5
g. Not applicable

13. Provide the number of interns that work during your shift?
    a. 0
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. >5
    h. Not applicable

14. Provide the number of pharmaceutical technicians and pharmaceutical technicians in training that work during your shift?
    a. 0
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. 6
    h. 7
    i. 8
    j. 9
    k. 10
    l. >10
    m. Not applicable

15. Provide the number of clerks/cashiers that work during your shift.
    a. 0
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. 6
    h. 7
    i. 8
    j. 9
    k. 10
    l. >10
    m. Not applicable

16. Do you believe your primary practice setting is sufficiently staffed to meet the demands of the pharmacy while meeting patient care and safety standards?
    a. Yes
    b. No

c. Not applicable

17. Do you believe the current staffing in your primary practice setting poses a risk to patient safety?
    a. Yes
    b. No
    c. Not applicable

18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?
    a. Additional pharmacists
    b. Additional pharmaceutical technicians
    c. Additional cashiers or clerks
    d. None. There is sufficient number of staff to meet the demands of the pharmacy.
    e. Not applicable

19. I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care.
    a. Strongly disagree
    b. Disagree
    c. Neither agree nor disagree
    d. Agree
    e. Strongly agree
    f. Not applicable

20. I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care.
    a. Strongly disagree
    b. Disagree
    c. Neither agree nor disagree
    d. Agree
    e. Strongly agree
    f. Not applicable

21. I feel that staffing at my pharmacy is adequate to prevent delays in patients receiving medications in a timely manner.
    a. Strongly disagree
    b. Disagree
    c. Neither agree nor disagree
    d. Agree
    e. Strongly agree
    f. Not applicable

22. On average, what number of prescriptions or chart orders do YOU process during your shift?
    a. 1-100
    b. 101-200
    c. 201-300
    d. 301-400
    e. 401-500
    f. 501-600
    g. 601-700
    h. >700
    i. Unsure/Varies

j. Not applicable

23. On average, how many vaccines do YOU administer or supervise the administration of during your shift?
    a. 1-20
    b. 21-40
    c. 41-60
    d. 61-80
    e. 81-100
    f. >100
    g. Unsure/Varies
    h. Not applicable

24. Does your primary practice setting perform sterile or non-sterile compounding?
    a. Yes
    b. No
    c. Not applicable

25. Which of the following services are provided at your primary practice setting?
    a. Immunization
    b. Administration of medications and biologics
    c. CLIA waived tests
    d. Hormonal Contraception
    e. Smoking Cessation
    f. PrEP and PEP prescribing and dispensing
    g. Medication Therapy Management
    h. Other
    i. Not applicable
    j. None of the above

26. Does your employer require you to complete non-dispensing related services, such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects?
    a. Yes
    b. No
    c. Not applicable

27. On average, what percentage of your time is spent on non-dispensing services?
    a. 1-25%
    b. 26-50%
    c. 51-75%
    d. 76-100%
    e. Not applicable

28. In your opinion, how does completing non-dispensing services affect your ability to dispense prescriptions effectively?
    a. It greatly diminishes my ability to dispense prescriptions effectively.
    b. It somewhat diminishes my ability to dispense prescriptions effectively.
    c. It does not affect my ability to dispense prescriptions effectively.
    d. Not applicable

29. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect your ability to practice safely?
    a. It greatly diminishes my ability to practice safely.
    b. It somewhat diminishes my ability to practice safely.
    c. It does not affect my ability to practice safely.
    d. Not applicable

30. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect patients from getting their medications in a timely manner?
    a. It greatly diminishes patients from getting their medications in a timely manner.
    b. It somewhat diminishes patients from getting their medications in a timely manner.
    c. It does not affect patients from getting their medications in a timely manner.
    d. Not applicable

31. Does your employer at your primary practice setting use workload metrics to measure one or more of following areas: number of immunizations, number of refill requests, number of patients enrolled in autofill, number of prescriptions filled, number of MTM services completed, average time to fill a new prescription, average time to fill a refill, average wait time for prescriptions, OR other metrics?
    a. Yes
    b. No
    c. Not applicable

32. Do you feel that you have been pressured by your employer or supervisor to meet standards or metrics that may interfere with safe patient care?
    a. Yes
    b. Somewhat
    c. No
    d. Not applicable

33. On average, how frequently are you interrupted while processing a prescription?
    a. Always
    b. Usually
    c. Sometimes
    d. Rarely
    e. Never
    f. Not applicable

34. Do you fear that interruptions while processing a prescription may lead to a medication error?
    a. Yes
    b. No
    c. Not applicable

35. In your opinion, how do interruptions while processing a prescription affect your ability to practice safely?
    a. It greatly affects my ability to practice safely.
    b. It somewhat affects my ability to practice safely.
    c. It does not affect my ability to practice safely.
    d. Not applicable

    According to the National Coordinating Council for Medication Error Reporting and Prevention, a "medication error" is defined as "any preventable event that ***may cause*** or ***lead*** to inappropriate

medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

36. What is the average number of medication errors **that leave the pharmacy**, if any, do you believe occur monthly at your primary practice setting?
    a. 1-5
    b. 6-10
    c. 11-15
    d. 16-20
    e. 21-25
    f. 26-30
    g. >30
    h. None
    i. Unknown
    j. Not applicable

37. What is the average number of medication errors **that were caught before it left the pharmacy**, if any, do you believe occur monthly at your primary practice setting?
    a. 1-5
    b. 6-10
    c. 11-15
    d. 16-20
    e. 21-25
    f. 26-30
    g. >30
    h. None
    i. Unknown
    j. Not applicable

38. In your opinion, how would an increase in the number of Pharmaceutical Technicians (PT) and Pharmaceutical Technicians in Training (PTT) you may supervise in your primary practice setting affect *patient safety*?
    a. Improve patient safety
    b. Worsen patient safety
    c. No impact on patient safety
    d. No opinion
    e. Not applicable

39. In your opinion, how would an increase in the number of PTs and PTTs you may supervise in your primary practice setting affect *medication errors*?
    a. Decrease medication errors
    b. Increase medication errors
    c. No effect on the number of medication errors
    d. No opinion
    e. Not applicable

40. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect *patient safety*?
    a. Improve patient safety

b. Worsen patient safety
c. No impact on patient safety
d. No opinion
e. Not applicable

41. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect *medication errors*?
    a. Decrease medication errors
    b. Increase medication errors
    c. No effect on the number of medication errors
    d. No opinion
    e. Not applicable

42. In your opinion, is your primary practice setting a safe work environment that prioritizes patient care and safety?
    a. Yes
    b. No
    c. Not applicable

43. Does your pharmacy employer provide you with meal periods and rest periods?
    a. Yes
    b. No
    c. Not applicable

44. Are your meal periods and rest periods uninterrupted?
    a. Yes
    b. No
    c. Not applicable

45. In your opinion, are you able to comfortably take meals and rest periods without feeling like you will fall behind or compromise patient care or safety?
    a. Yes
    b. No
    c. Not applicable

46. Did your employer require you to voluntarily agree to forego any rest period or meal period as a condition of your employment?
    a. Yes
    b. No
    c. Not applicable

47. Please rank the following from 1 to 7 on their impact on patient safety (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety).
    a. Eliminating workload productivity metrics
    b. Eliminating non-dispensing responsibilities for pharmacists processing prescriptions
    c. Eliminating non-patient related interruptions for pharmacists processing prescriptions
    d. Beginning your workday without a backlog of work from the previous shift or day
    e. Increasing the number of pharmacists staffed
    f. Increasing the number of pharmaceutical technicians staffed
    g. Increasing the number of cashiers staffed

48. My current workload is:
    a. Excessively low
    b. Low
    c. About Right
    d. High
    e. Excessively High
    f. Not applicable

49. Compared to pre-pandemic, my workload has:
    a. Significantly decreased
    b. Decreased
    c. Remained the same
    d. Increased
    e. Significantly increased
    f. Not applicable

50. I feel my employer provides a work environment that allows for safe patient care.
    a. Strongly disagree
    b. Disagree
    c. Neither agree nor disagree
    d. Agree
    e. Strongly agree
    f. Not applicable

51. I feel safe voicing any workplace concerns to my employer.
    a. Strongly disagree
    b. Disagree
    c. Neither agree nor disagree
    d. Agree
    e. Strongly agree
    f. Not applicable

52. Have you quit or left a pharmacy employment due to patient safety concerns?
    a. Yes
    b. No
    c. Not applicable

53. If you answered "yes" to question 52, what pharmacy practice setting did you leave?
    a. Institutional/Hospital Pharmacy
    b. Retail Chain Pharmacy
    c. Independent Pharmacy
    d. Department of Defense or Veterans Affairs Pharmacy
    e. Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)
    f. Consultant Pharmacist Position
    g. Not applicable

54. In your opinion, what is the number of prescriptions ***ONE*** pharmacist should be able to **reasonably and safely fill** on a given weekday, working from 9am to 7pm, in a **general retail pharmacy** setting, with the assistance of one to three pharmaceutical technicians or pharmaceutical technicians in training ***IF*** non-dispensing services such as medication therapy management, vaccinations, point-of-

care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects **ARE EXCLUDED**?

a. <100 prescriptions
b. 101-200 prescriptions
c. 201-300 prescriptions
d. 301-400 prescriptions
e. 401-500 prescriptions
f. 501-600 prescriptions
g. 601-700 prescriptions
h. >700 prescriptions
i. Unknown
j. Not applicable

55. What workplace conditions, if any, do you believe should be addressed at your primary practice setting to promote patient safety? What suggestions do you have for improving the condition?

56. What other recommendations for changes do you have that you believe would lead to improved patient care or patient safety?

57. Please share any other comments you may have:

Well-Being Index Questions

58. Have you felt burned out from your work?
    a. Yes
    b. Somewhat
    c. No
    d. Not applicable
59. Does your job often negatively affect your mental or physical health?
    e. Yes
    f. Somewhat
    g. No
    h. Not applicable
60. Have you often been bothered by feeling down, anxious, irritable, depressed, or hopeless because of work?
    i. Yes
    j. Somewhat
    k. No
    l. Not applicable
61. Have you felt all things you had to do at work were piling up so high you could not overcome them?
    m. Yes
    n. Somewhat
    o. No
    p. Not applicable

Survey Results

Question 1 of the survey was removed from the results as it is confidential. Question 1 asked the pharmacist completing the survey to provide their Nevada pharmacist license number. The results of Question 1 were used strictly as a means to (1) limit the population of survey participants to Nevada-registered pharmacists and (2) excluding duplicate surveys.

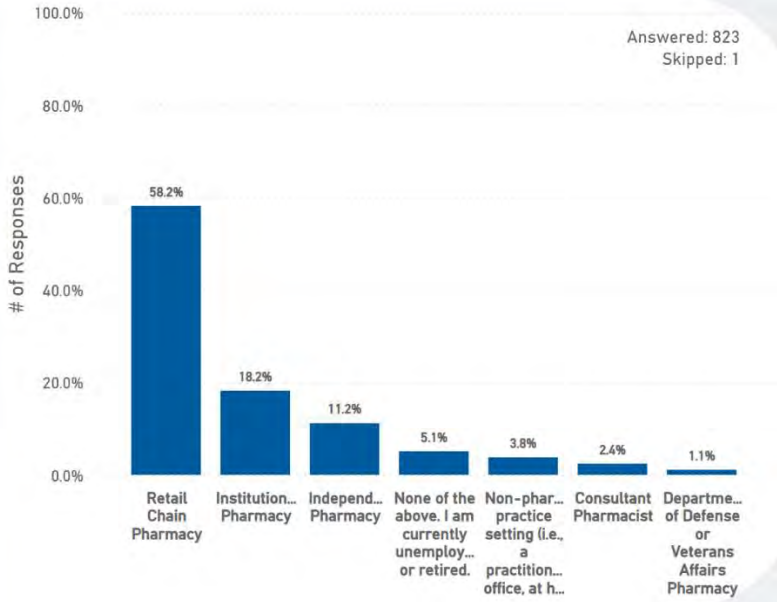
Additionally, with the exception of survey question 3, four statistical results are provided for each survey question depending on how the pharmacist answered question 3 of the survey. The four statistical results represent the following:

1. **All Responses** – is the statistical results from all survey participants
2. **Retail Chain Pharmacists** – is the statistical results from pharmacists that indicated their primary practice setting is in a Retail Chain Pharmacy
3. **Institutional/Hospital Pharmacist** – is the statistical results from pharmacists that indicated their primary practice setting is in an Institutional/Hospital Pharmacy
4. **Other** – is the statistical results from pharmacists from all other practice settings
    - Independent Pharmacy,
    - Consultant Pharmacist,
    - Department of Defense or Veterans Affairs Pharmacy,
    - Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.), and
    - None of the above. I am currently unemployed or retired.

3. Which of the following most closely describes your primary practice setting?

Survey Responses	# Responses	% Responses
Retail Chain Pharmacy	479	58.2%
Institutional/Hospital Pharmacy	150	18.2%
Independent Pharmacy	92	11.2%
None of the above. I am currently unemployed or retired.	42	5.1%
Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)	31	3.8%
Consultant Pharmacist	20	2.4%
Department of Defense or Veterans Affairs Pharmacy	9	1.1%
Total	**823**	**100.0%**

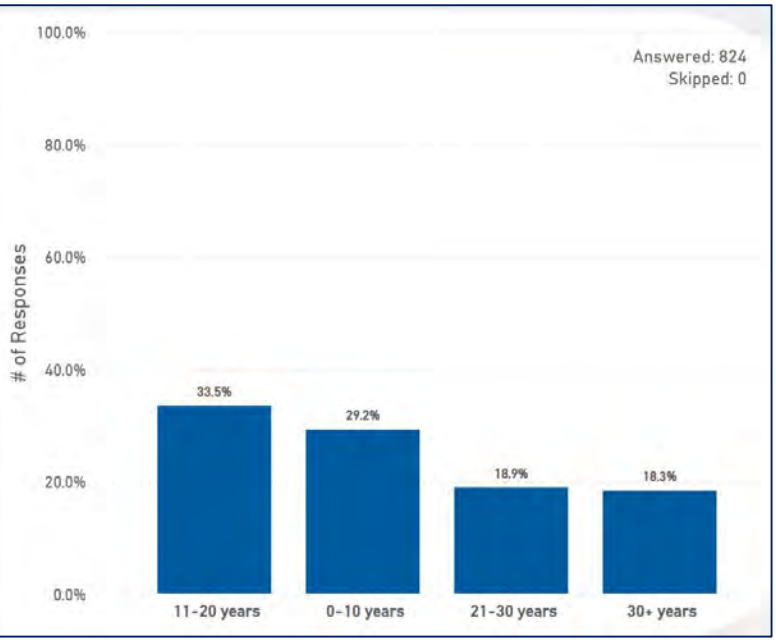
All Responses



2. How many years have you been in the practice of pharmacy?

Survey Responses	# Responses	% Responses
11-20 years	276	33.5%
0-10 years	241	29.2%
21-30 years	156	18.9%
30+ years	151	18.3%
Total	**824**	**100.0%**

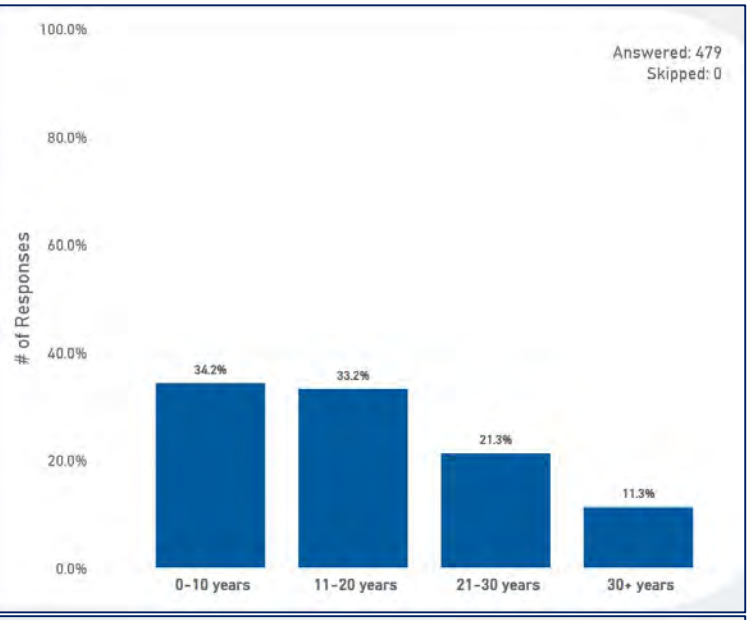
All Responses



2. How many years have you been in the practice of pharmacy?

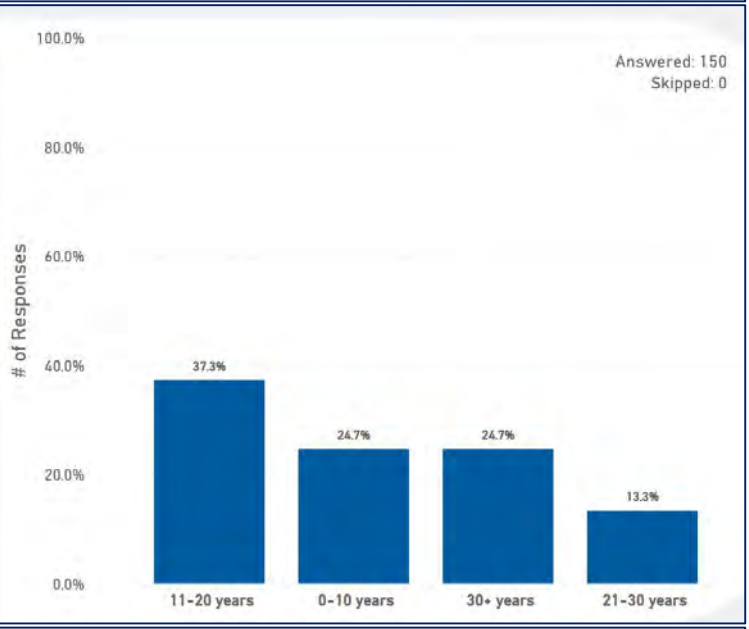
Survey Responses	# Responses	% Responses
0-10 years	164	34.2%
11-20 years	159	33.2%
21-30 years	102	21.3%
30+ years	54	11.3%
Total	**479**	**100.0%**

Retail Chain Pharmacists



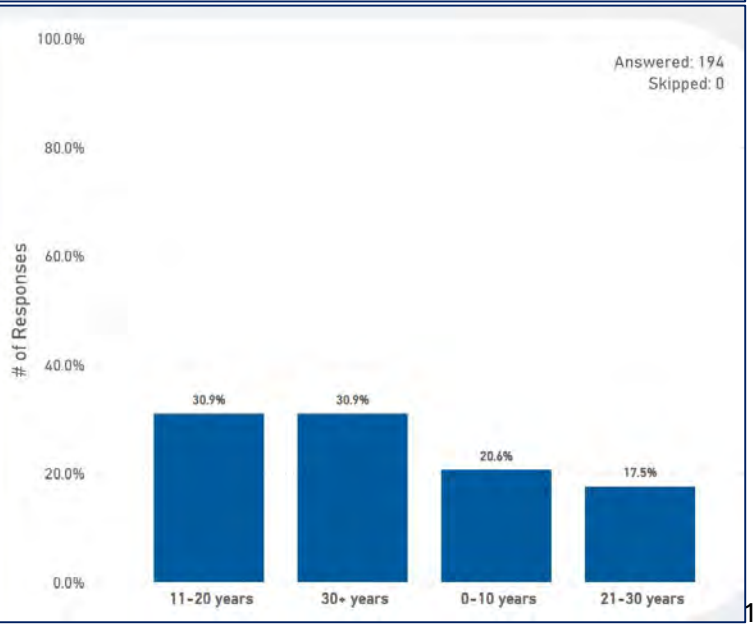
Survey Responses	# Responses	% Responses
11-20 years	56	37.3%
0-10 years	37	24.7%
30+ years	37	24.7%
21-30 years	20	13.3%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
11-20 years	60	30.9%
30+ years	60	30.9%
0-10 years	40	20.6%
21-30 years	34	17.5%
Total	**194**	**100.0%**

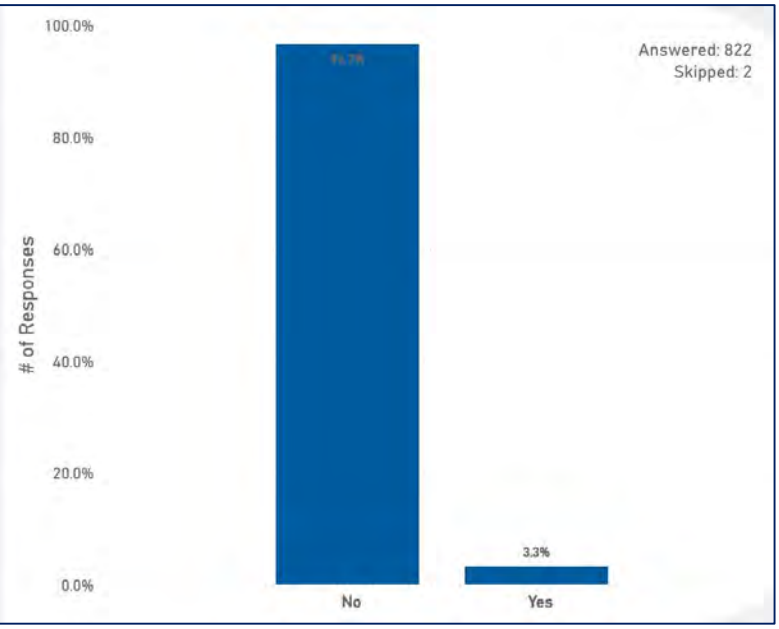
Other



4. Are you the owner of the pharmacy where you primarily practice?

Survey Responses	# Responses	% Responses
No	795	96.7%
Yes	27	3.3%
Total	**822**	**100.0%**

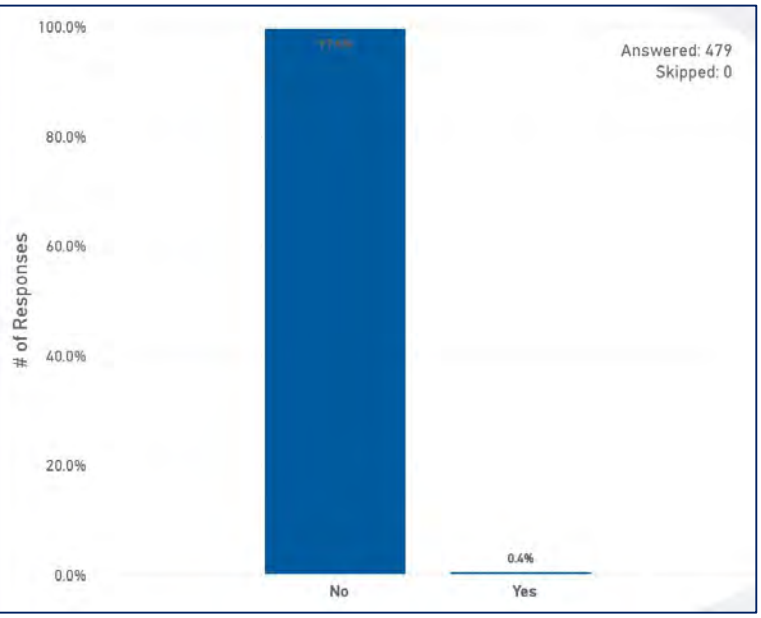
All Responses



4. Are you the owner of the pharmacy where you primarily practice?

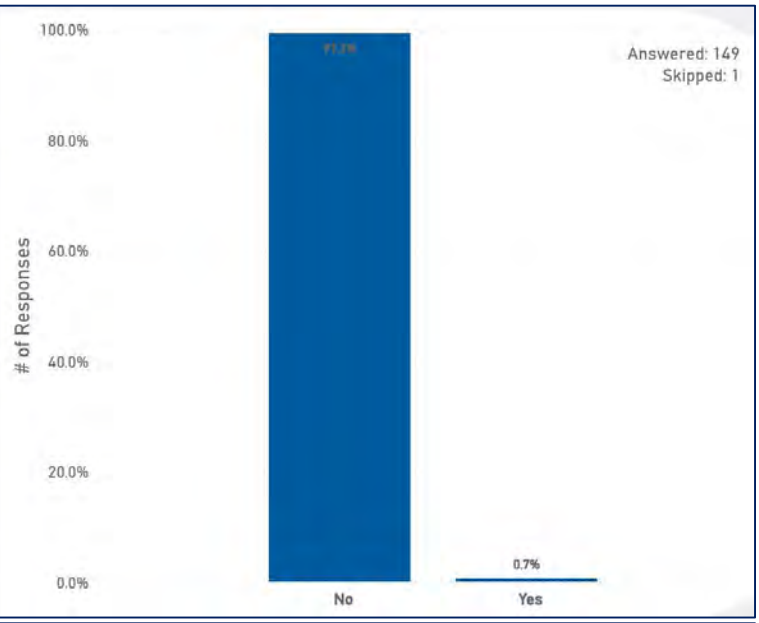
Survey Responses	# Responses	% Responses
No	477	99.6%
Yes	2	0.4%
Total	**479**	**100.0%**

Retail Chain Pharmacist



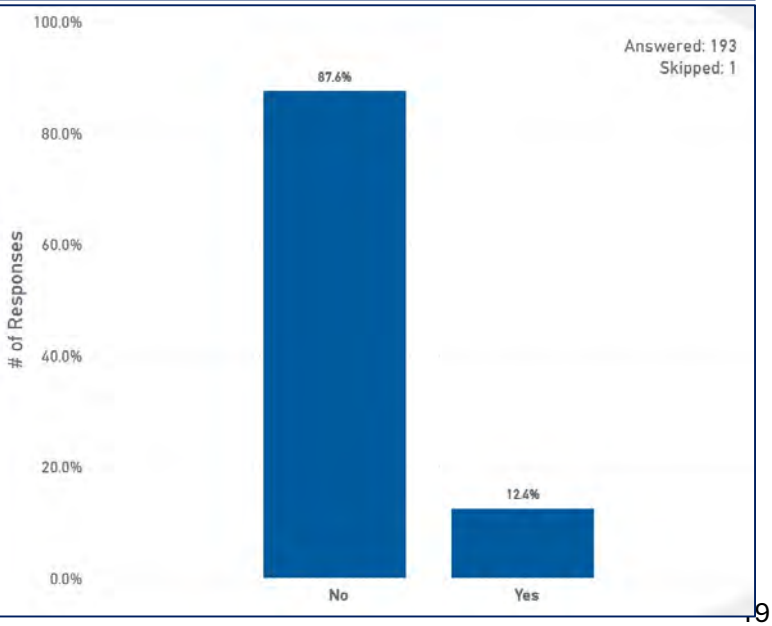
Survey Responses	# Responses	% Responses
No	148	99.3%
Yes	1	0.7%
Total	**149**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
No	169	87.6%
Yes	24	12.4%
Total	**193**	**100.0%**

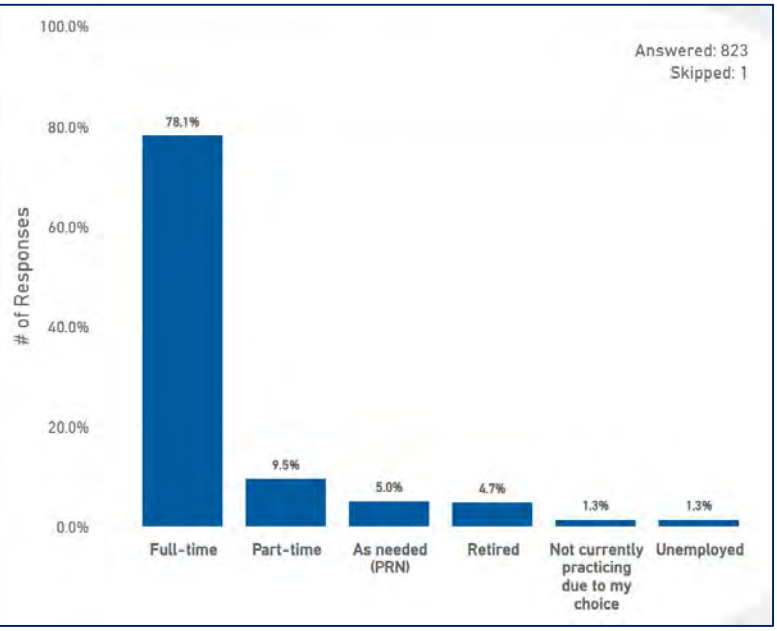
Other



5. What is your employment status?

Survey Responses	# Responses	% Responses
Full-time	643	78.1%
Part-time	78	9.5%
As needed (PRN)	41	5.0%
Retired	39	4.7%
Not currently practicing due to my choice	11	1.3%
Unemployed	11	1.3%
Total	**823**	**100.0%**

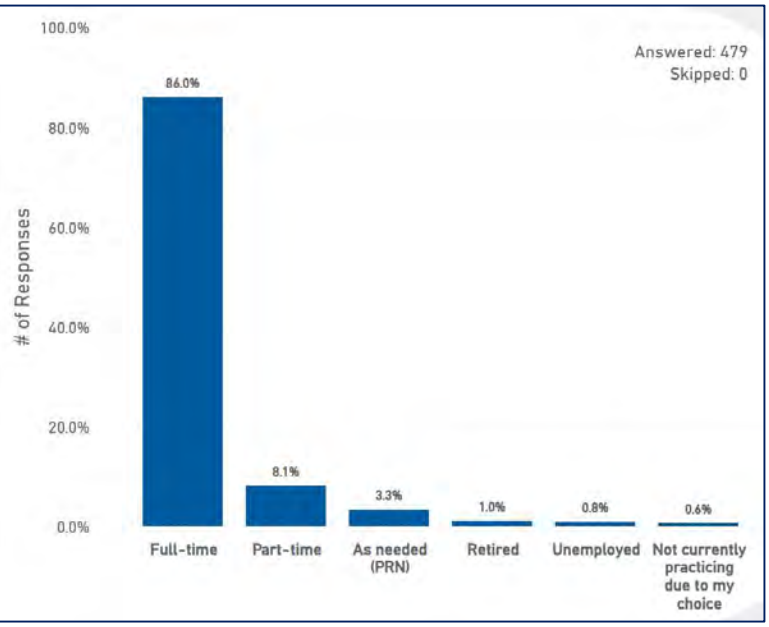
All Responses



5. What is your employment status?

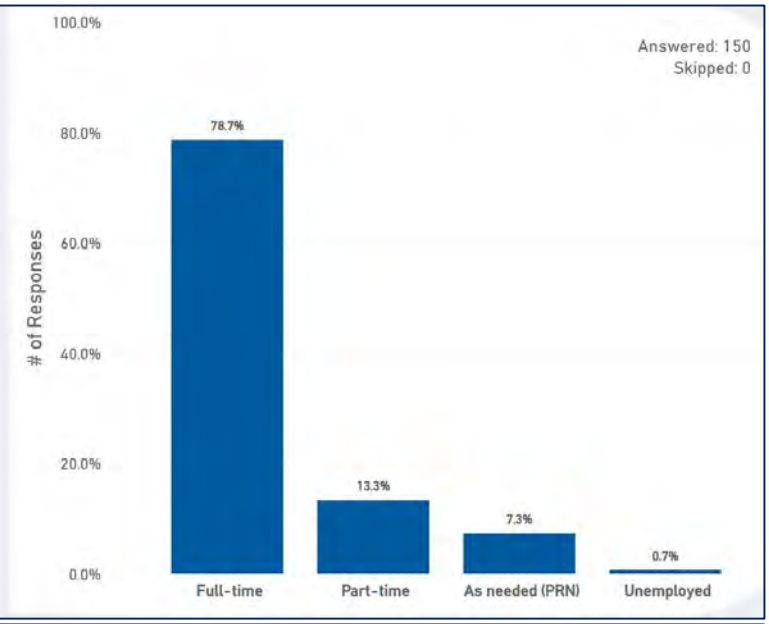
Survey Responses	# Responses	% Responses
Full-time	412	86.0%
Part-time	39	8.1%
As needed (PRN)	16	3.3%
Retired	5	1.0%
Unemployed	4	0.8%
Not currently practicing due to my choice	3	0.6%
Total	**479**	**100.0%**

Retail Chain Pharmacist



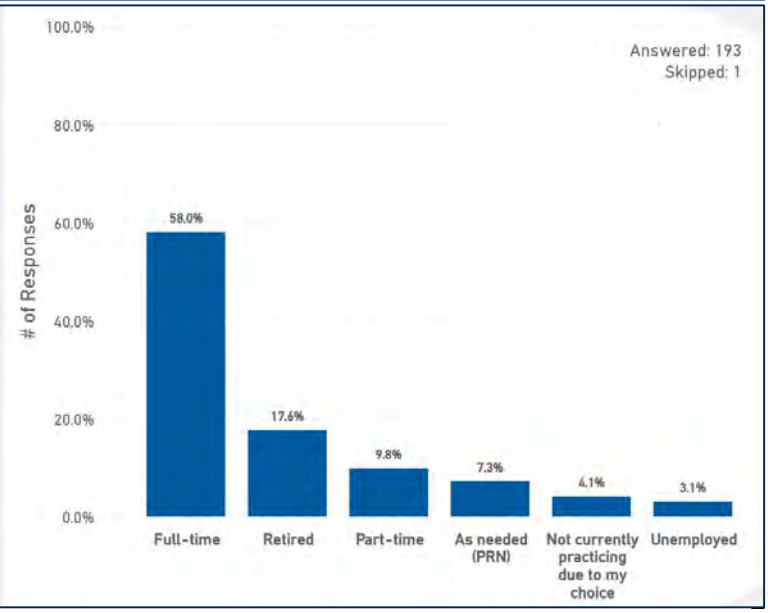
Survey Responses	# Responses	% Responses
Full-time	118	78.7%
Part-time	20	13.3%
As needed (PRN)	11	7.3%
Unemployed	1	0.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Full-time	112	58.0%
Retired	34	17.6%
Part-time	19	9.8%
As needed (PRN)	14	7.3%
Not currently practicing due to my choice	8	4.1%
Unemployed	6	3.1%
Total	**193**	**100.0%**

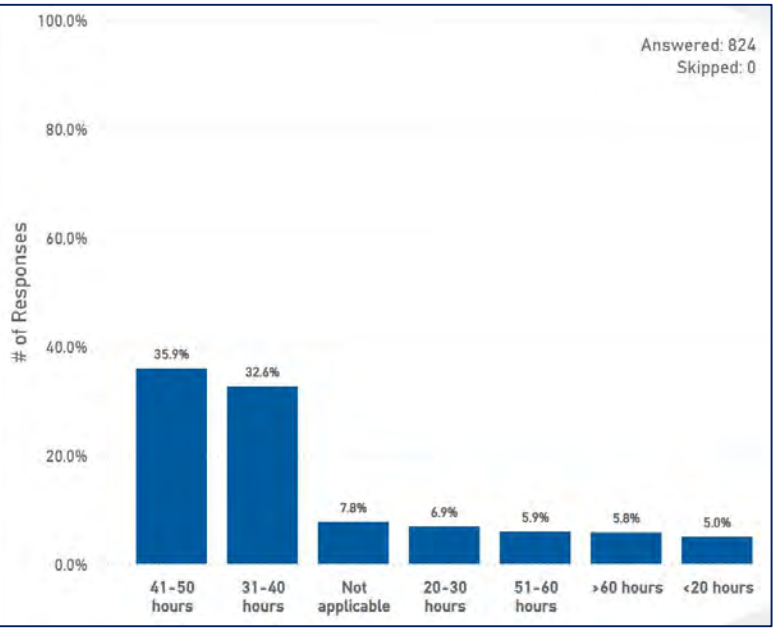
Other



6. How many hours per week do you work at your primary practice setting (please include paid and unpaid hours)?

Survey Responses	# Responses	% Responses
41-50 hours	296	35.9%
31-40 hours	269	32.6%
Not applicable	64	7.8%
20-30 hours	57	6.9%
51-60 hours	49	5.9%
>60 hours	48	5.8%
<20 hours	41	5.0%
Total	**824**	**100.0%**

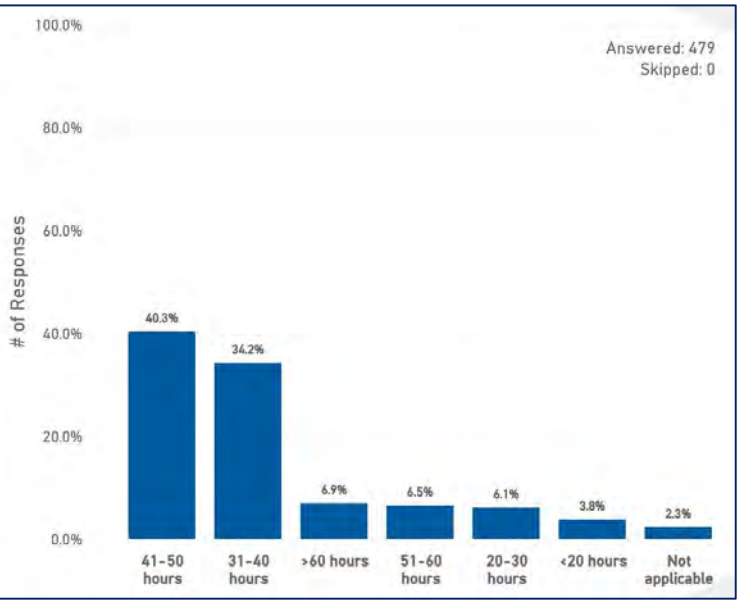
All Responses



6. How many hours per week do you work at your primary practice setting (please include paid and unpaid hours)?

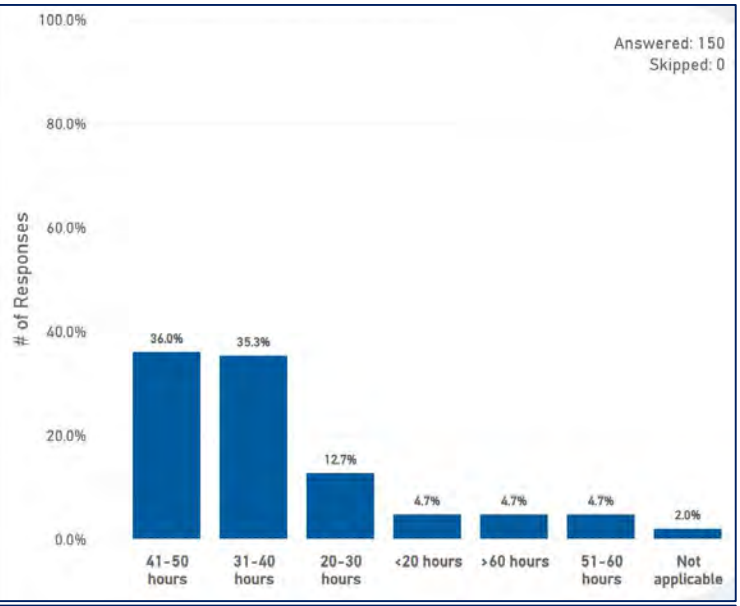
Survey Responses	# Responses	% Responses
41-50 hours	193	40.3%
31-40 hours	164	34.2%
>60 hours	33	6.9%
51-60 hours	31	6.5%
20-30 hours	29	6.1%
<20 hours	18	3.8%
Not applicable	11	2.3%
Total	**479**	**100.0%**

Retail Chain Pharmacist



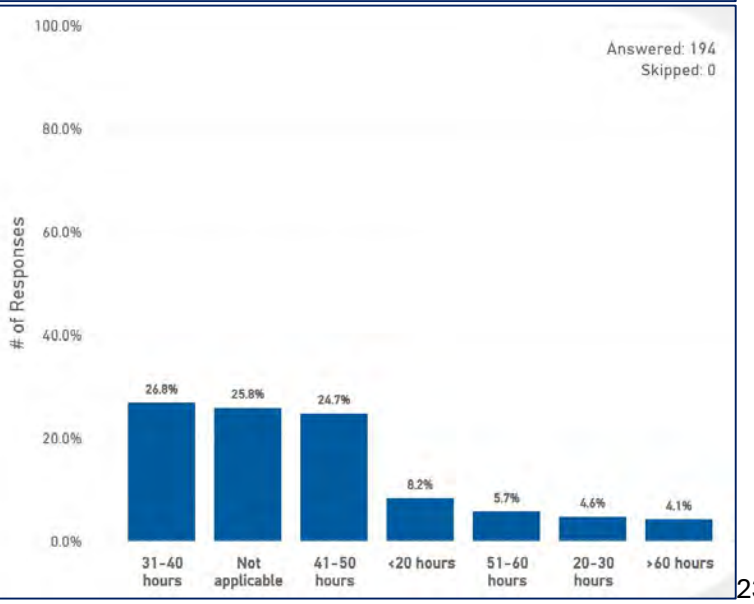
Survey Responses	# Responses	% Responses
41-50 hours	54	36.0%
31-40 hours	53	35.3%
20-30 hours	19	12.7%
<20 hours	7	4.7%
>60 hours	7	4.7%
51-60 hours	7	4.7%
Not applicable	3	2.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
31-40 hours	52	26.8%
Not applicable	50	25.8%
41-50 hours	48	24.7%
<20 hours	16	8.2%
51-60 hours	11	5.7%
20-30 hours	9	4.6%
>60 hours	8	4.1%
Total	**194**	**100.0%**

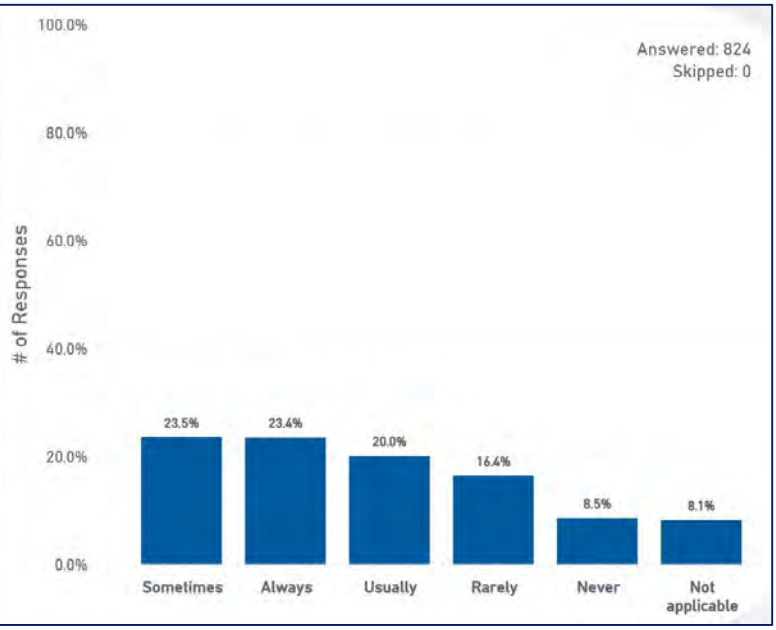
Other



7. To keep up with work related tasks, how often do you continue working after your scheduled/paid shift hours have been completed?

Survey Responses	# Responses	% Responses
Sometimes	194	23.5%
Always	193	23.4%
Usually	165	20.0%
Rarely	135	16.4%
Never	70	8.5%
Not applicable	67	8.1%
Total	**824**	**100.0%**

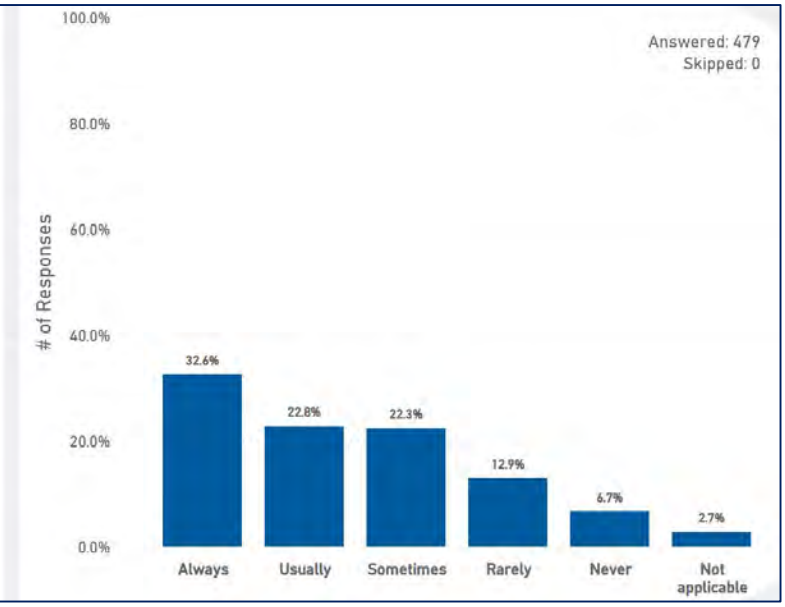
All Responses



7. To keep up with work related tasks, how often do you continue working after your scheduled/paid shift hours have been completed?

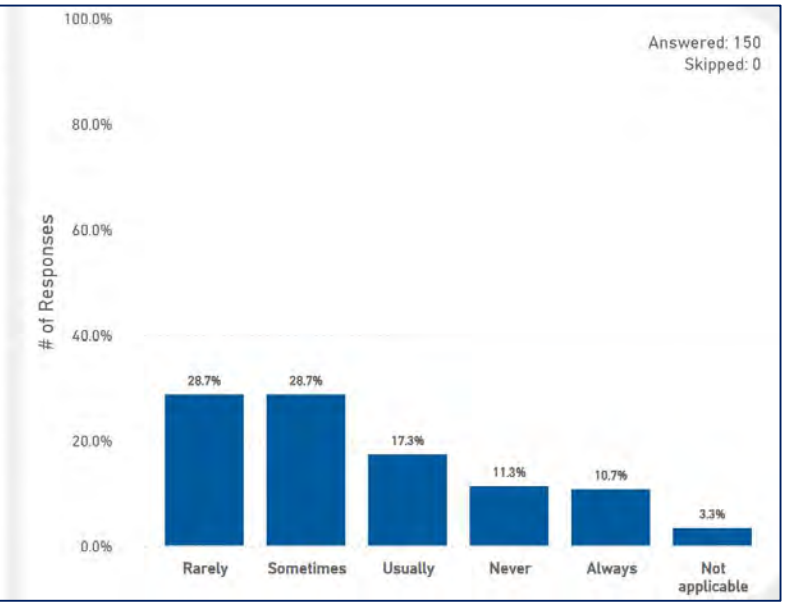
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Always	156	32.6%
Usually	109	22.8%
Sometimes	107	22.3%
Rarely	62	12.9%
Never	32	6.7%
Not applicable	13	2.7%
Total	**479**	**100.0%**



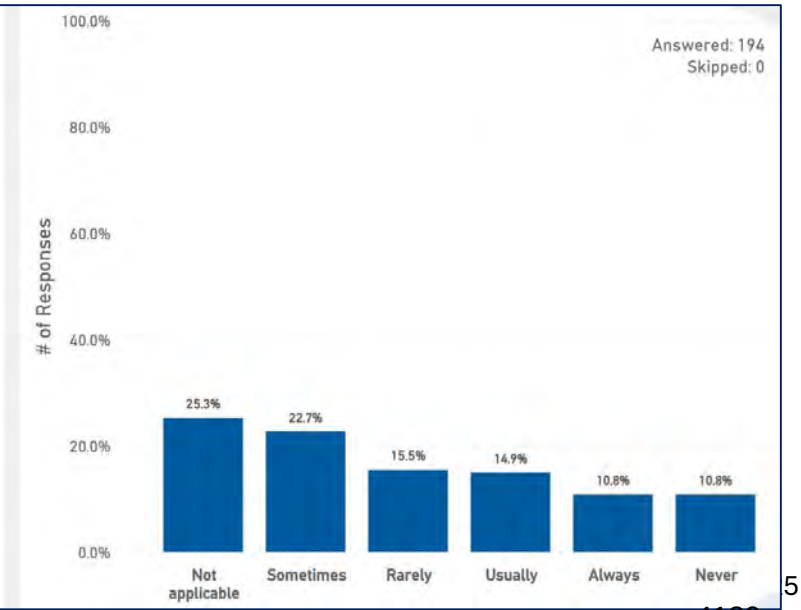
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Rarely	43	28.7%
Sometimes	43	28.7%
Usually	26	17.3%
Never	17	11.3%
Always	16	10.7%
Not applicable	5	3.3%
Total	**150**	**100.0%**



Other

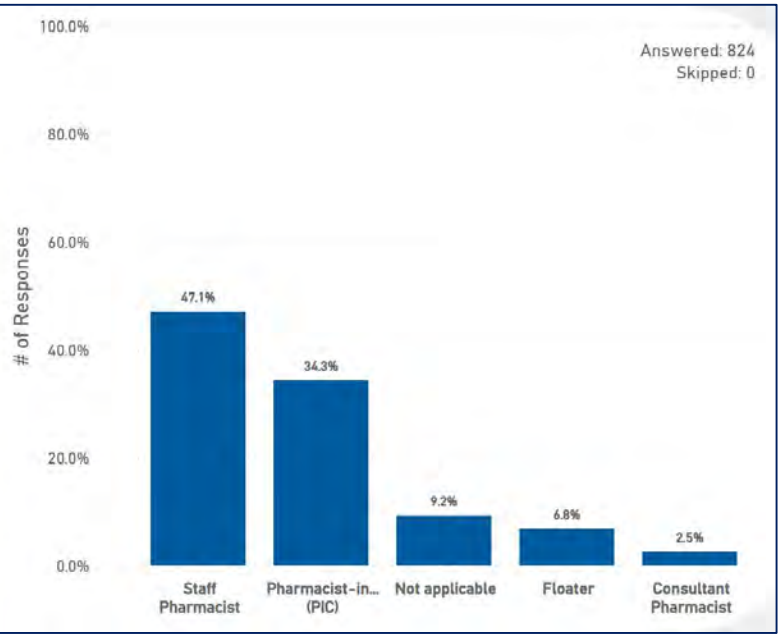
Survey Responses	# Responses	% Responses
Not applicable	49	25.3%
Sometimes	44	22.7%
Rarely	30	15.5%
Usually	29	14.9%
Always	21	10.8%
Never	21	10.8%
Total	**194**	**100.0%**



8. What is your role at your primary practice setting?

Survey Responses	# Responses	% Responses
Staff Pharmacist	388	47.1%
Pharmacist-in-charge (PIC)	283	34.3%
Not applicable	76	9.2%
Floater	56	6.8%
Consultant Pharmacist	21	2.5%
Total	**824**	**100.0%**

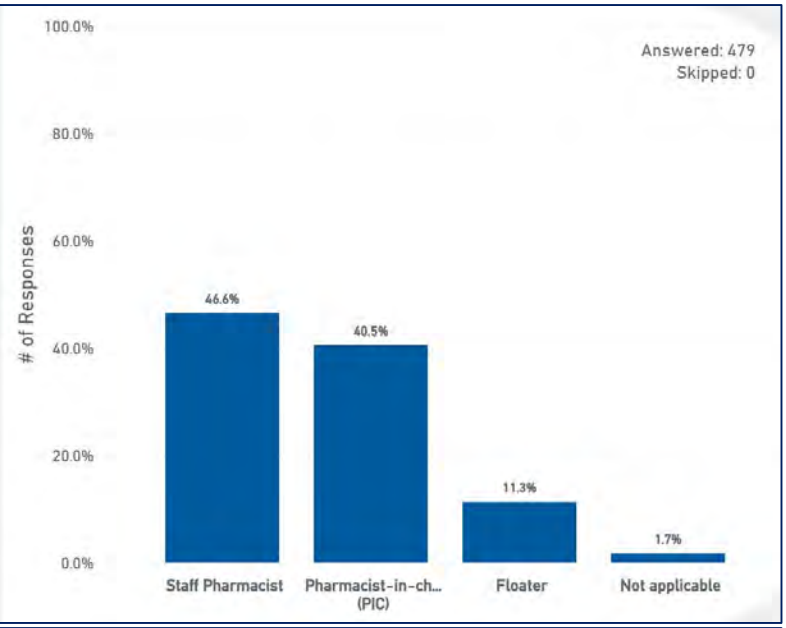
All Responses



8. What is your role at your primary practice setting?

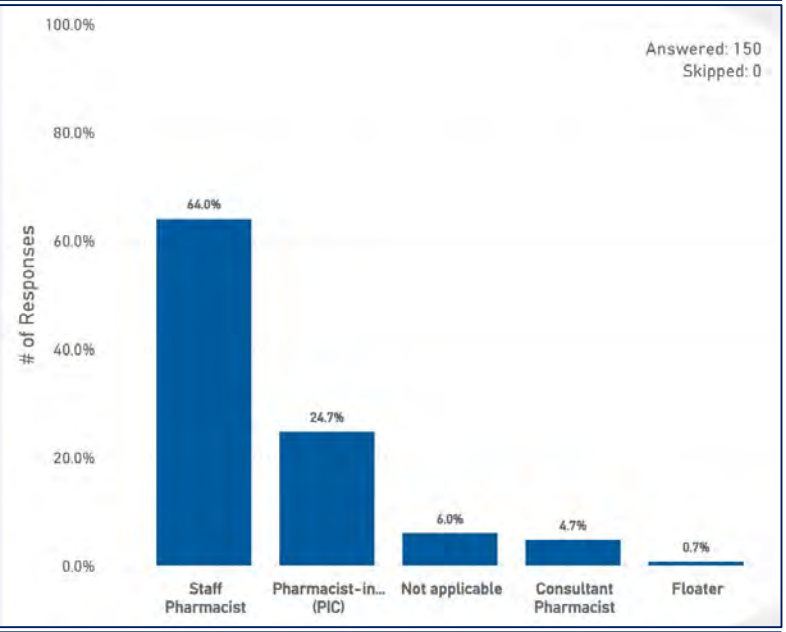
Survey Responses	# Responses	% Responses
Staff Pharmacist	223	46.6%
Pharmacist-in-charge (PIC)	194	40.5%
Floater	54	11.3%
Not applicable	8	1.7%
Total	**479**	**100.0%**

Retail Chain Pharmacist



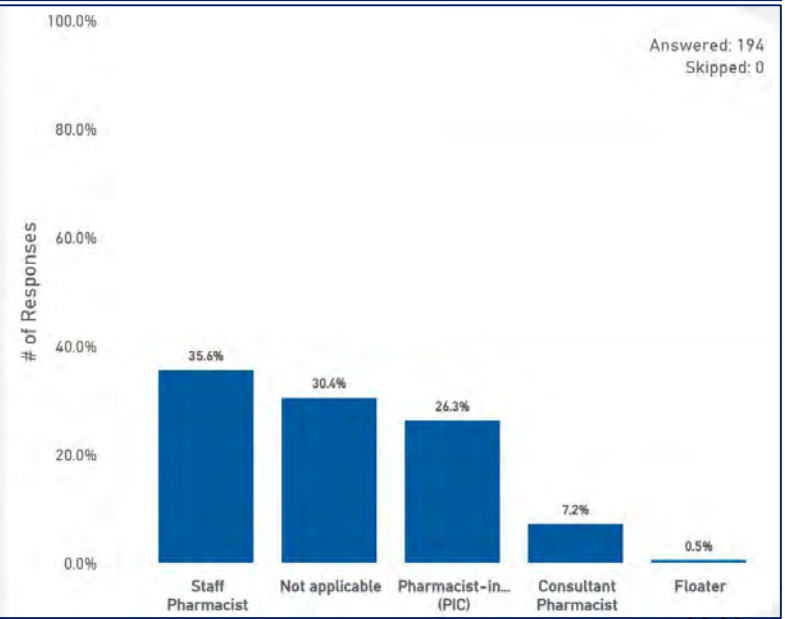
Survey Responses	# Responses	% Responses
Staff Pharmacist	96	64.0%
Pharmacist-in-charge (PIC)	37	24.7%
Not applicable	9	6.0%
Consultant Pharmacist	7	4.7%
Floater	1	0.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Staff Pharmacist	69	35.6%
Not applicable	59	30.4%
Pharmacist-in-charge (PIC)	51	26.3%
Consultant Pharmacist	14	7.2%
Floater	1	0.5%
Total	**194**	**100.0%**

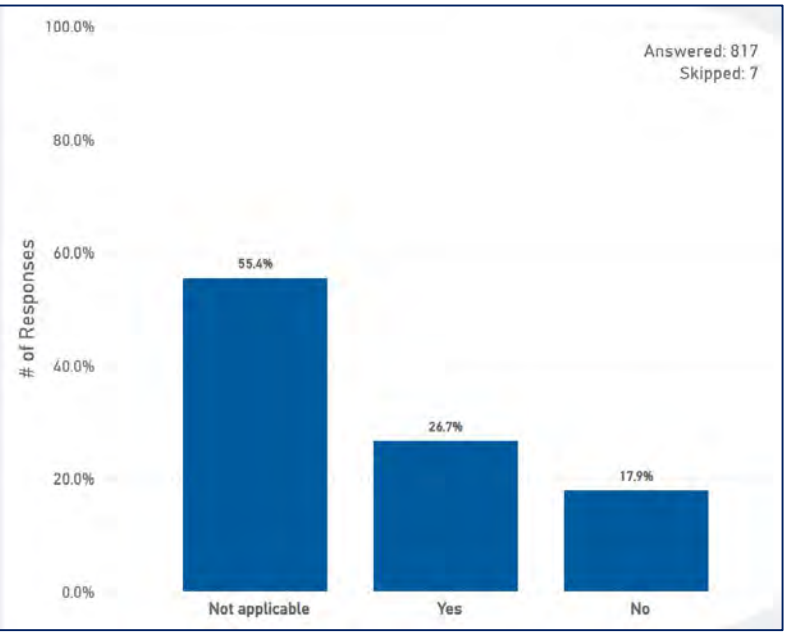
Other



9. If you are the designated PIC, do you feel you have sufficient autonomy and power to fulfill your duties as the PIC?

Survey Responses	# Responses	% Responses
Not applicable	453	55.4%
Yes	218	26.7%
No	146	17.9%
Total	**817**	**100.0%**

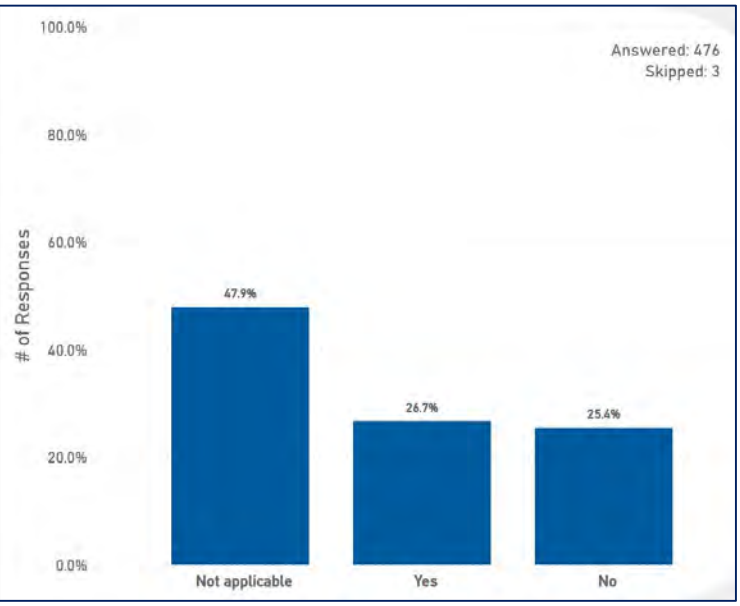
All Responses



9. If you are the designated PIC, do you feel you have sufficient autonomy and power to fulfill your duties as the PIC?

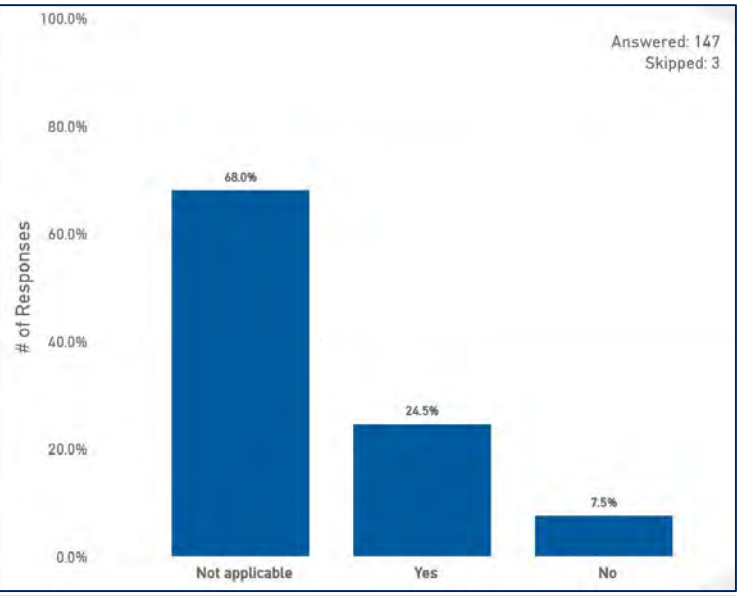
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Not applicable	228	47.9%
Yes	127	26.7%
No	121	25.4%
Total	**476**	**100.0%**



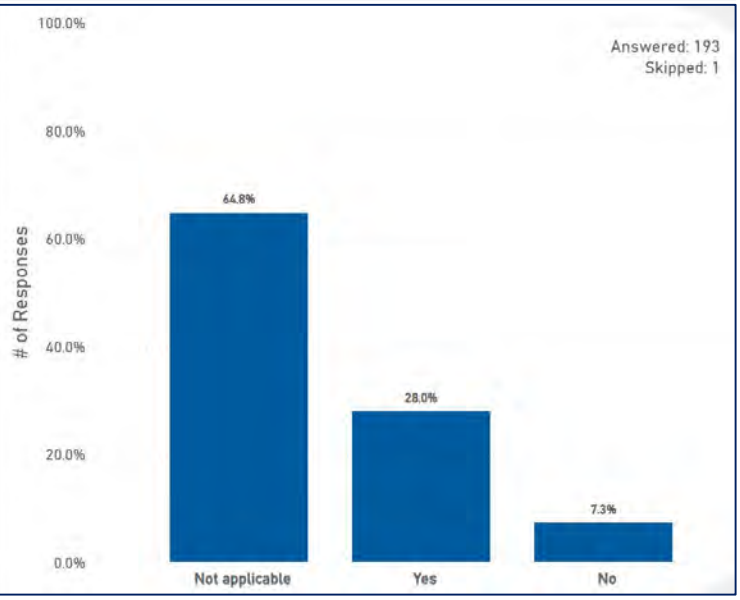
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Not applicable	100	68.0%
Yes	36	24.5%
No	11	7.5%
Total	**147**	**100.0%**



Other

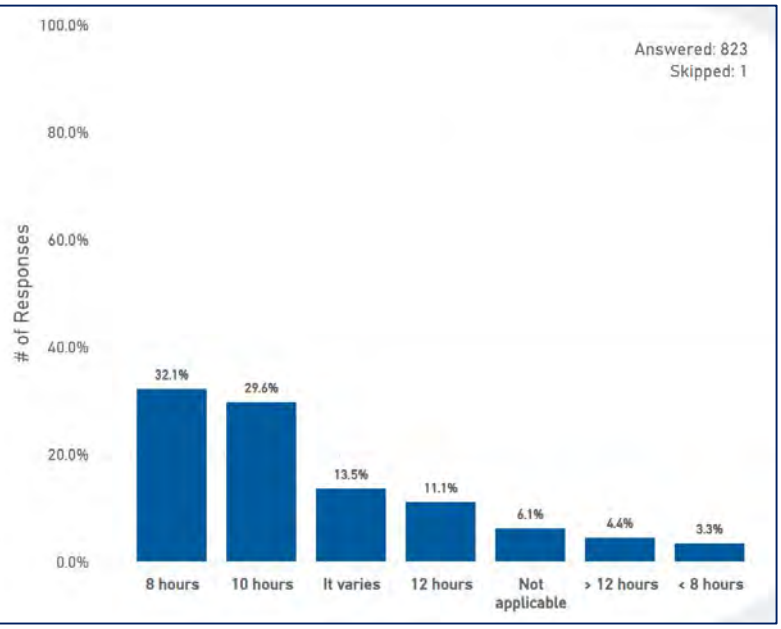
Survey Responses	# Responses	% Responses
Not applicable	125	64.8%
Yes	54	28.0%
No	14	7.3%
Total	**193**	**100.0%**



10. How long is a typical work shift at your primary practice setting?

Survey Responses	# Responses	% Responses
8 hours	264	32.1%
10 hours	244	29.6%
It varies	111	13.5%
12 hours	91	11.1%
Not applicable	50	6.1%
› 12 hours	36	4.4%
‹ 8 hours	27	3.3%
Total	**823**	**100.0%**

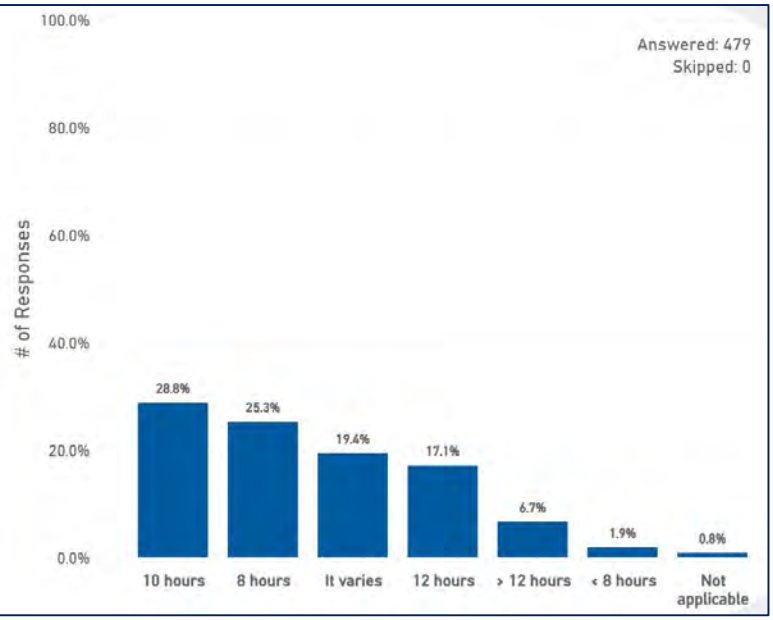
All Responses



10. How long is a typical work shift at your primary practice setting?

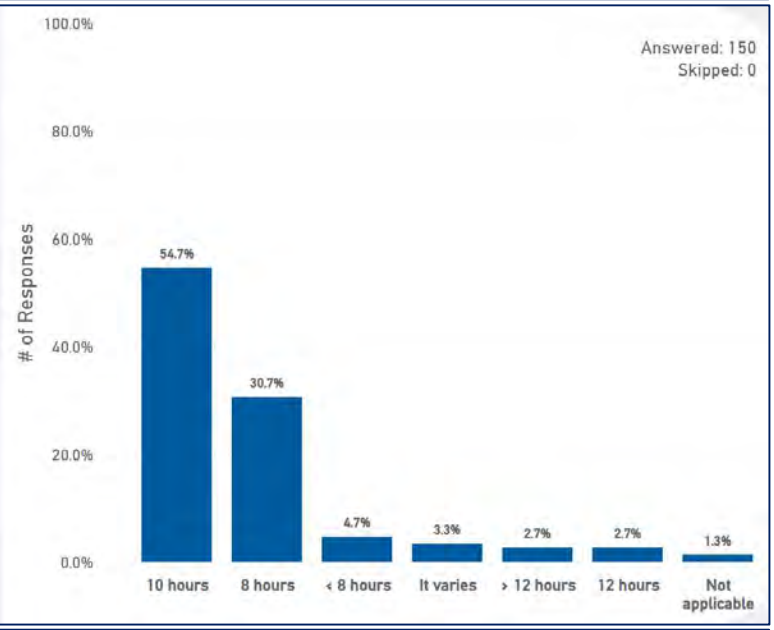
Survey Responses	# Responses	% Responses
10 hours	138	28.8%
8 hours	121	25.3%
It varies	93	19.4%
12 hours	82	17.1%
› 12 hours	32	6.7%
‹ 8 hours	9	1.9%
Not applicable	4	0.8%
Total	**479**	**100.0%**

Retail Chain Pharmacist



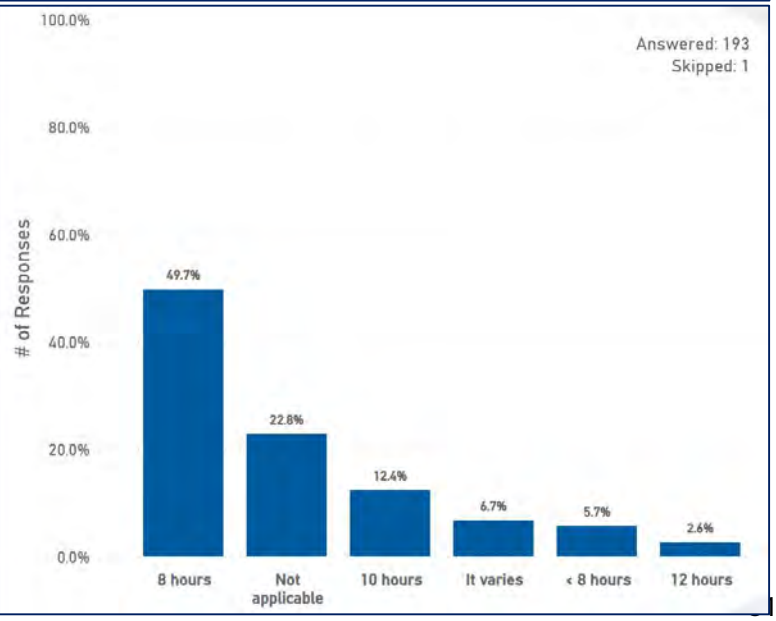
Survey Responses	# Responses	% Responses
10 hours	82	54.7%
8 hours	46	30.7%
‹ 8 hours	7	4.7%
It varies	5	3.3%
› 12 hours	4	2.7%
12 hours	4	2.7%
Not applicable	2	1.3%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
8 hours	96	49.7%
Not applicable	44	22.8%
10 hours	24	12.4%
It varies	13	6.7%
‹ 8 hours	11	5.7%
12 hours	5	2.6%
Total	**193**	**100.0%**

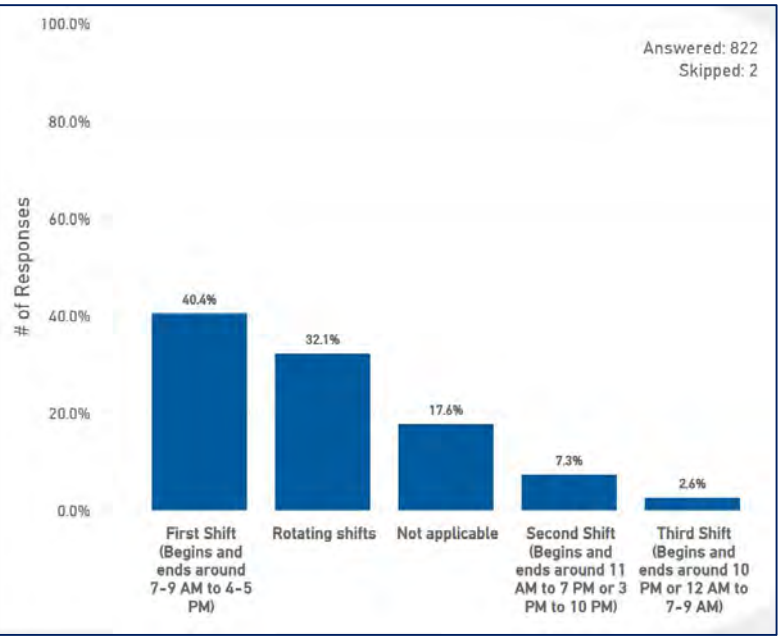
Other



11. Which of the following most closely describes the shift you work at your primary practice setting?

Survey Responses	# Responses	% Responses
First Shift (Begins and ends around 7-9 AM to 4-5 PM)	332	40.4%
Rotating shifts	264	32.1%
Not applicable	145	17.6%
Second Shift (Begins and ends around 11 AM to 7 PM or 3 PM to 10 PM)	60	7.3%
Third Shift (Begins and ends around 10 PM or 12 AM to 7-9 AM)	21	2.6%
Total	**822**	**100.0%**

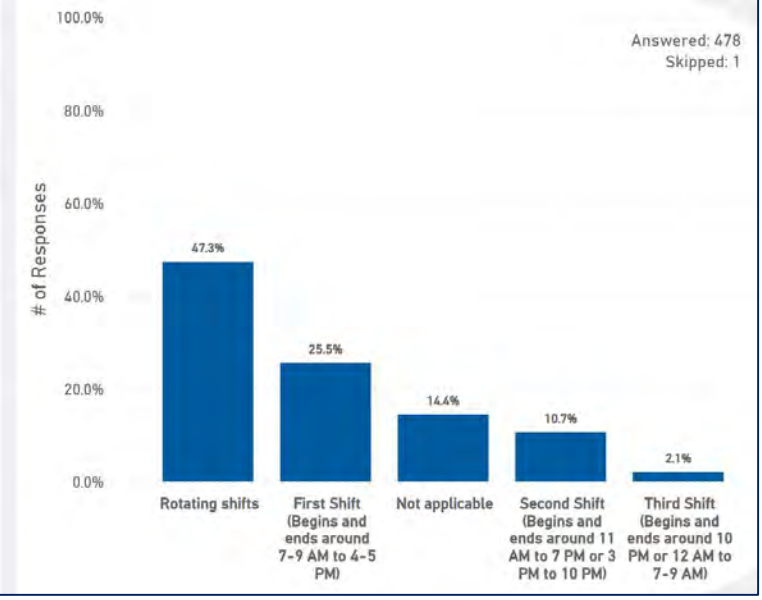
All Responses



11. Which of the following most closely describes the shift you work at your primary practice setting?

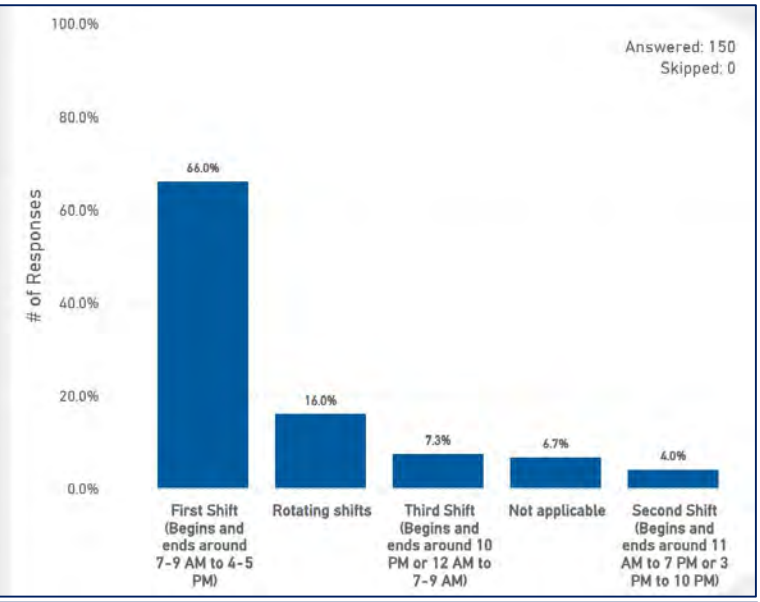
Survey Responses	# Responses	% Responses
Rotating shifts	226	47.3%
First Shift (Begins and ends around 7-9 AM to 4-5 PM)	122	25.5%
Not applicable	69	14.4%
Second Shift (Begins and ends around 11 AM to 7 PM or 3 PM to 10 PM)	51	10.7%
Third Shift (Begins and ends around 10 PM or 12 AM to 7-9 AM)	10	2.1%
Total	**478**	**100.0%**

Retail Chain Pharmacist



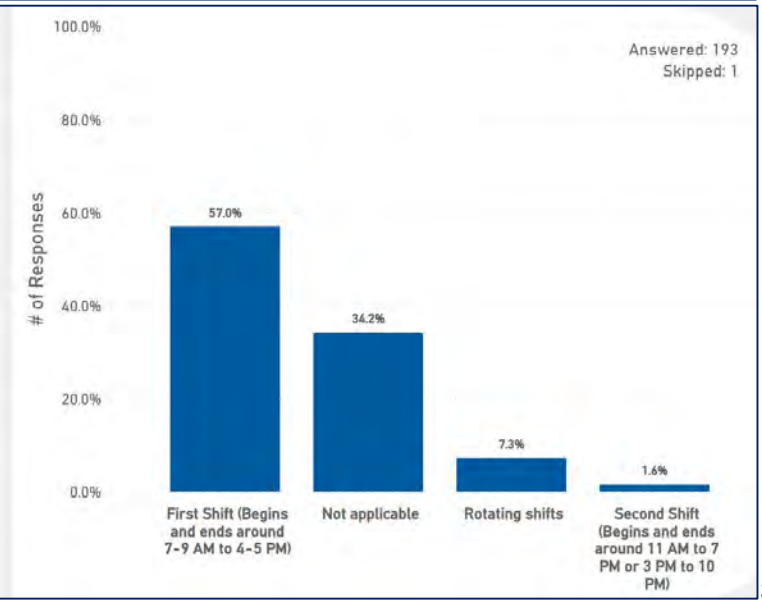
Survey Responses	# Responses	% Responses
First Shift (Begins and ends around 7-9 AM to 4-5 PM)	99	66.0%
Rotating shifts	24	16.0%
Third Shift (Begins and ends around 10 PM or 12 AM to 7-9 AM)	11	7.3%
Not applicable	10	6.7%
Second Shift (Begins and ends around 11 AM to 7 PM or 3 PM to 10 PM)	6	4.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
First Shift (Begins and ends around 7-9 AM to 4-5 PM)	110	57.0%
Not applicable	66	34.2%
Rotating shifts	14	7.3%
Second Shift (Begins and ends around 11 AM to 7 PM or 3 PM to 10 PM)	3	1.6%
Total	**193**	**100.0%**

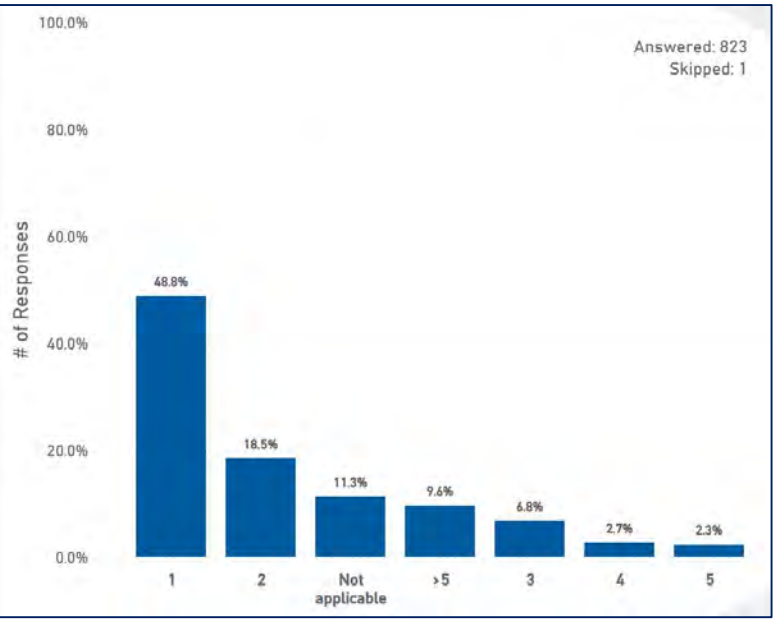
Other



12. Provide the number of pharmacists that work during your shift?

Survey Responses	# Responses	% Responses
1	402	48.8%
2	152	18.5%
Not applicable	93	11.3%
>5	79	9.6%
3	56	6.8%
4	22	2.7%
5	19	2.3%
Total	**823**	**100.0%**

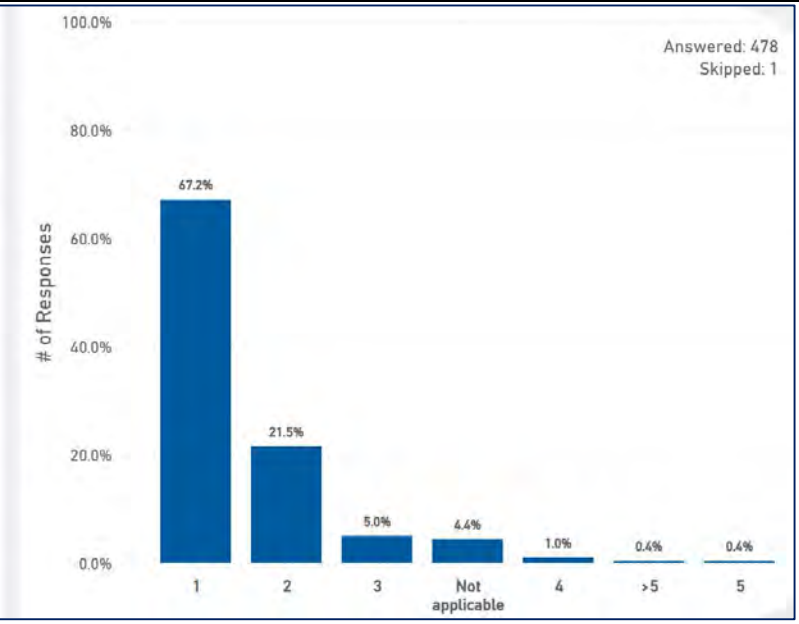
All Responses



12. Provide the number of pharmacists that work during your shift?

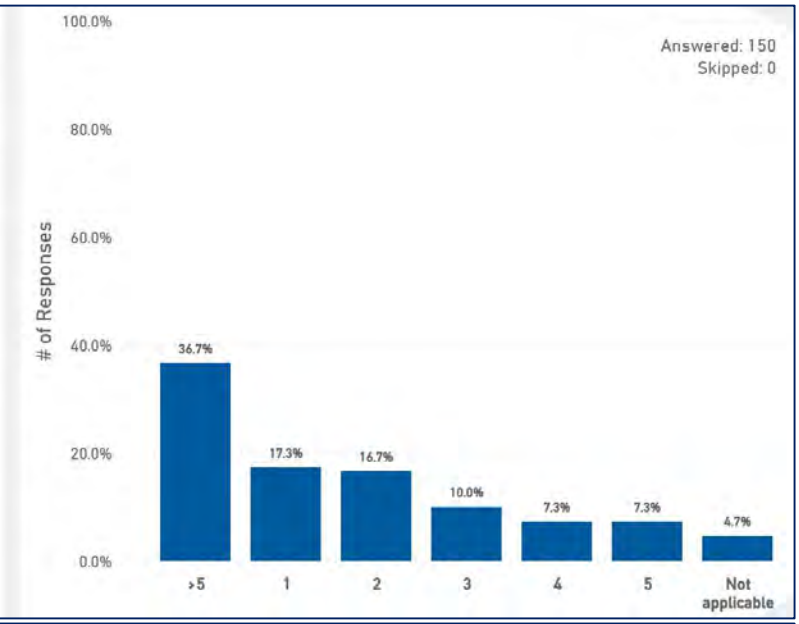
Survey Responses	# Responses	% Responses
1	321	67.2%
2	103	21.5%
3	24	5.0%
Not applicable	21	4.4%
4	5	1.0%
>5	2	0.4%
5	2	0.4%
Total	**478**	**100.0%**

Retail Chain Pharmacist



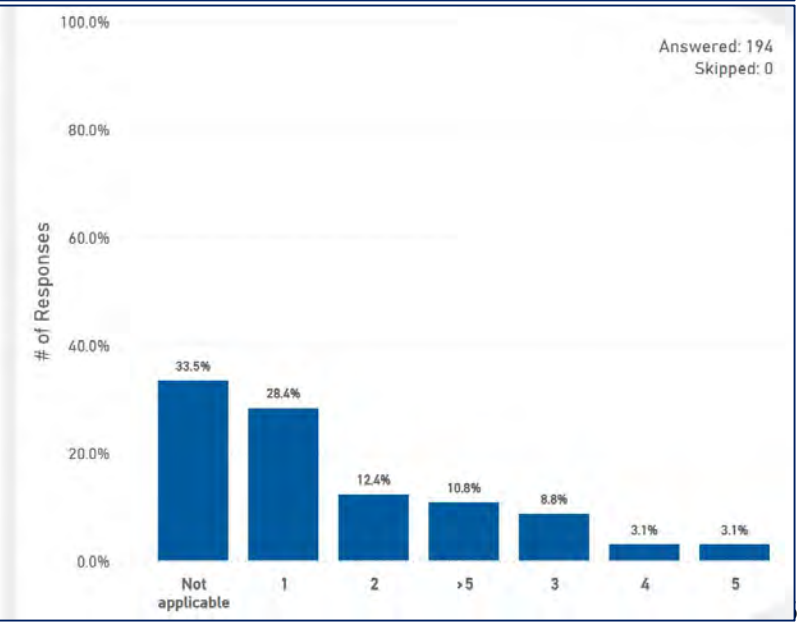
Survey Responses	# Responses	% Responses
>5	55	36.7%
1	26	17.3%
2	25	16.7%
3	15	10.0%
4	11	7.3%
5	11	7.3%
Not applicable	7	4.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	65	33.5%
1	55	28.4%
2	24	12.4%
>5	21	10.8%
3	17	8.8%
4	6	3.1%
5	6	3.1%
Total	**194**	**100.0%**

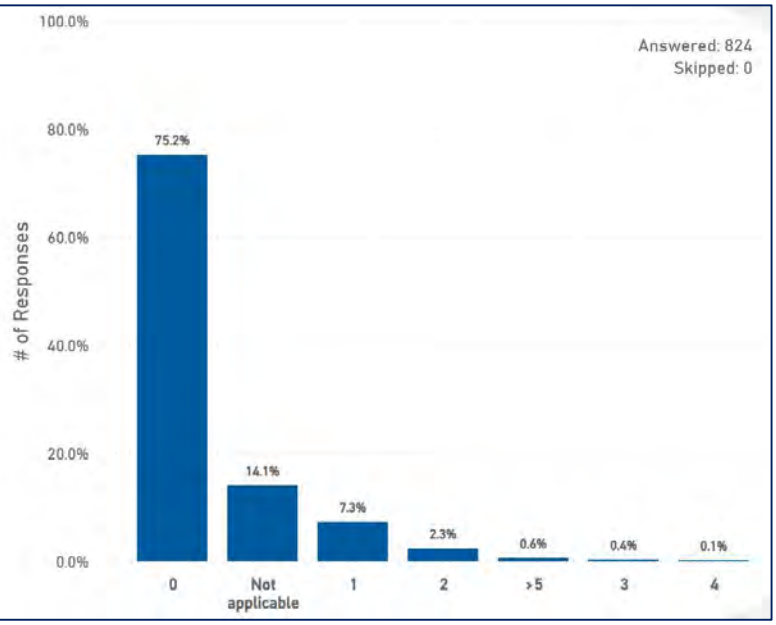
Other



13. Provide the number of interns that work during your shift?

Survey Responses	# Responses	% Responses
0	620	75.2%
Not applicable	116	14.1%
1	60	7.3%
2	19	2.3%
>5	5	0.6%
3	3	0.4%
4	1	0.1%
Total	**824**	**100.0%**

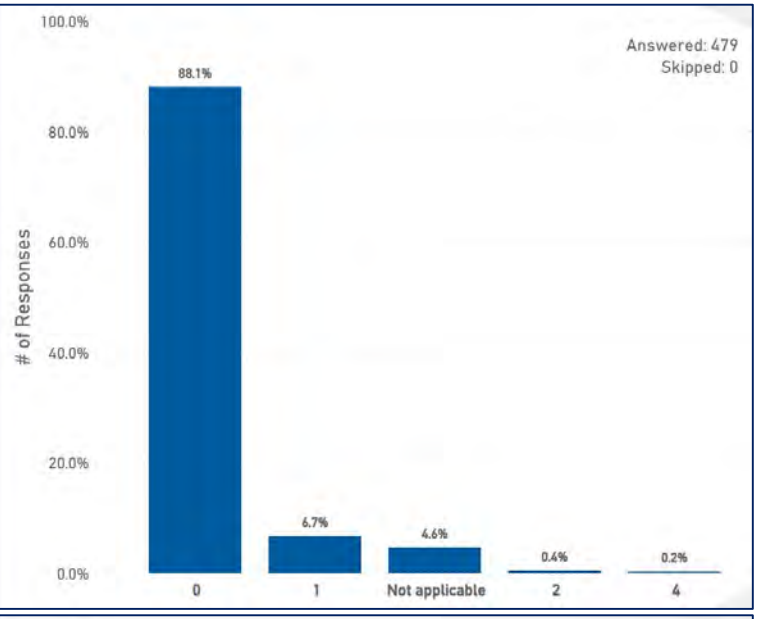
All Responses



13. Provide the number of interns that work during your shift?

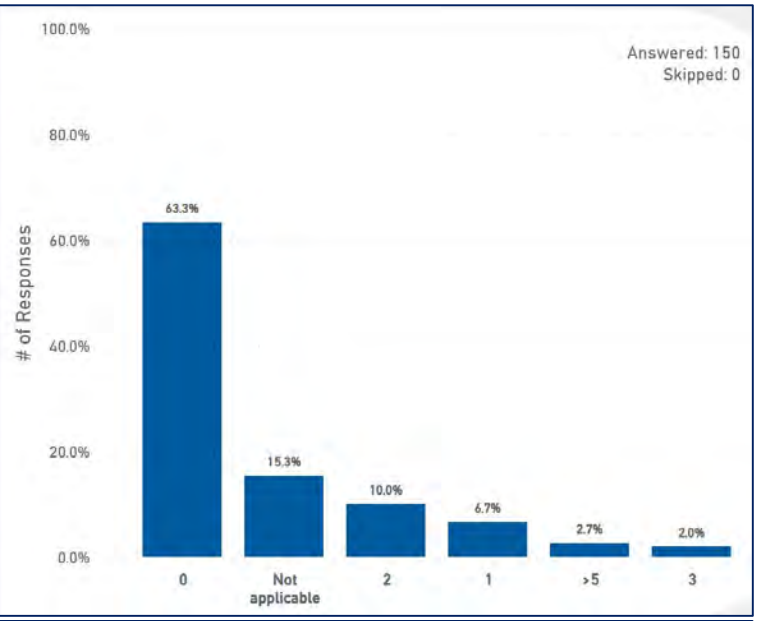
Survey Responses	# Responses	% Responses
0	422	88.1%
1	32	6.7%
Not applicable	22	4.6%
2	2	0.4%
4	1	0.2%
Total	**479**	**100.0%**

Retail Chain Pharmacist



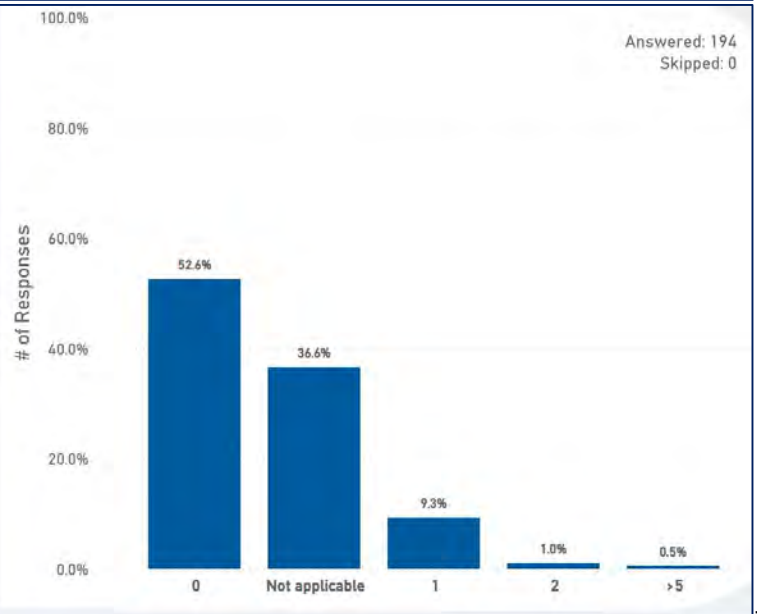
Survey Responses	# Responses	% Responses
0	95	63.3%
Not applicable	23	15.3%
2	15	10.0%
1	10	6.7%
>5	4	2.7%
3	3	2.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
0	102	52.6%
Not applicable	71	36.6%
1	18	9.3%
2	2	1.0%
>5	1	0.5%
Total	**194**	**100.0%**

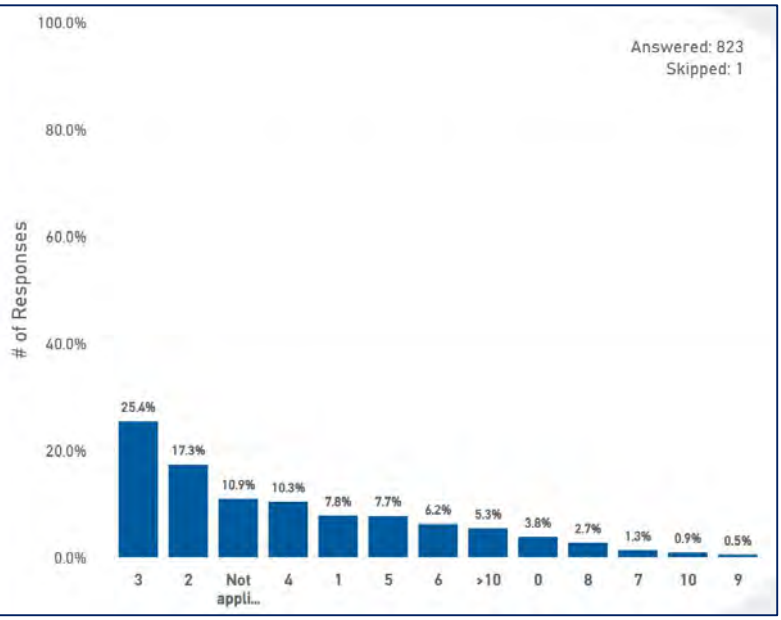
Other



14. Provide the number of pharmaceutical technicians and pharmaceutical technicians in training that work during your shift?

Survey Responses	# Responses	% Responses
3	209	25.4%
2	142	17.3%
Not applicable	90	10.9%
4	85	10.3%
1	64	7.8%
5	63	7.7%
6	51	6.2%
>10	44	5.3%
0	31	3.8%
8	22	2.7%
7	11	1.3%
10	7	0.9%
9	4	0.5%
Total	**823**	**100.0%**

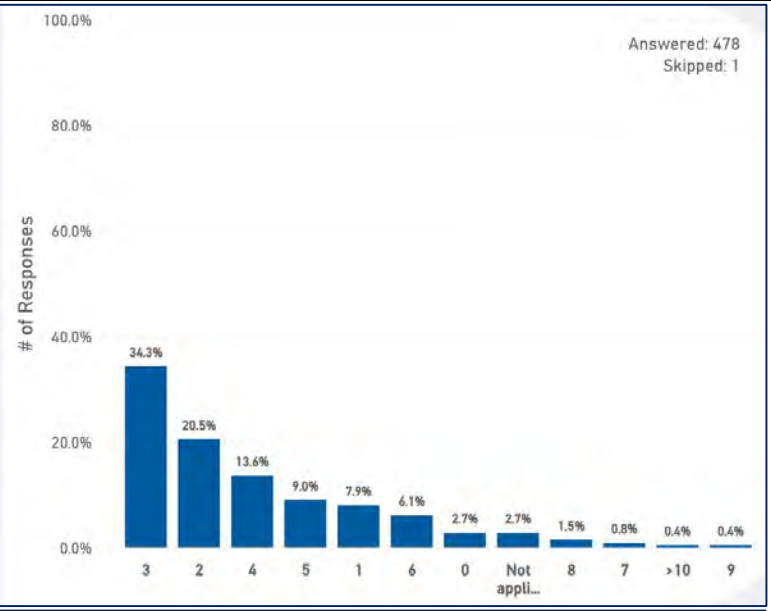
All Responses



14. Provide the number of pharmaceutical technicians and pharmaceutical technicians in training that work during your shift?

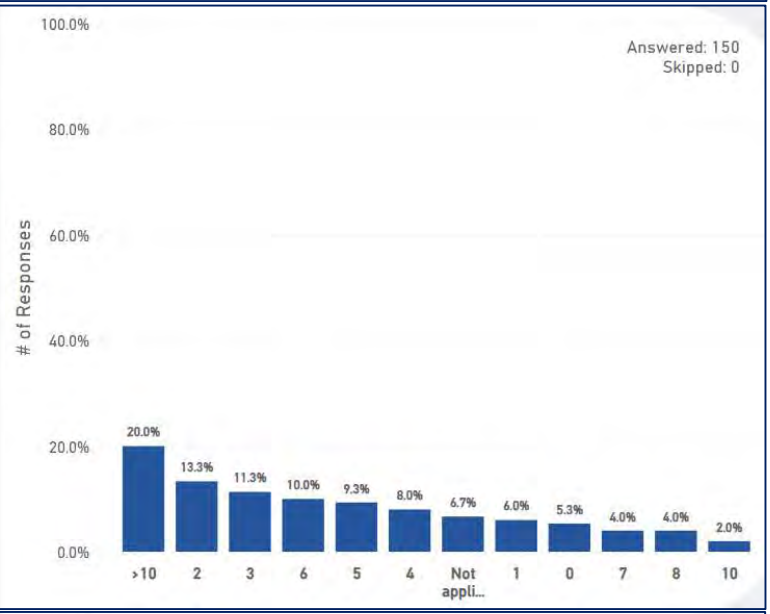
Survey Responses	# Responses	% Responses
3	164	34.3%
2	98	20.5%
4	65	13.6%
5	43	9.0%
1	38	7.9%
6	29	6.1%
0	13	2.7%
Not applicable	13	2.7%
8	7	1.5%
7	4	0.8%
>10	2	0.4%
9	2	0.4%
Total	**478**	**100.0%**

Retail Chain Pharmacist



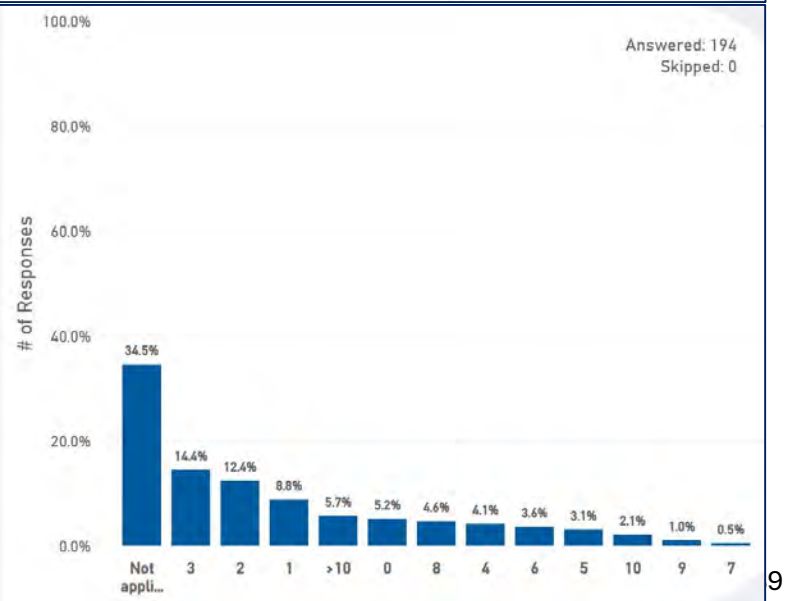
Survey Responses	# Responses	% Responses
>10	30	20.0%
2	20	13.3%
3	17	11.3%
6	15	10.0%
5	14	9.3%
4	12	8.0%
Not applicable	10	6.7%
1	9	6.0%
0	8	5.3%
7	6	4.0%
8	6	4.0%
10	3	2.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	67	34.5%
3	28	14.4%
2	24	12.4%
1	17	8.8%
>10	11	5.7%
0	10	5.2%
8	9	4.6%
4	8	4.1%
6	7	3.6%
5	6	3.1%
10	4	2.1%
9	2	1.0%
7	1	0.5%
Total	**194**	**100.0%**

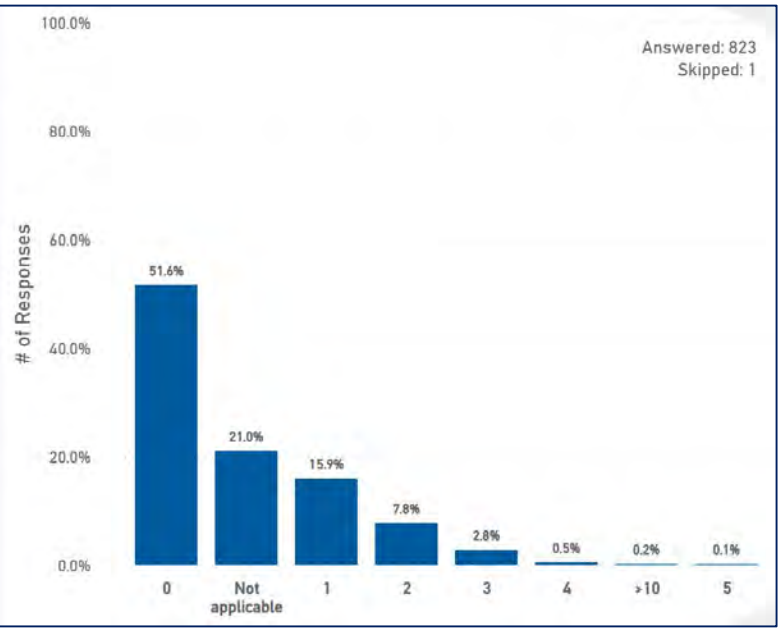
Other



15. Provide the number of clerks/cashiers that work during your shift.

Survey Responses	# Responses	% Responses
0	425	51.6%
Not applicable	173	21.0%
1	131	15.9%
2	64	7.8%
3	23	2.8%
4	4	0.5%
>10	2	0.2%
5	1	0.1%
Total	**823**	**100.0%**

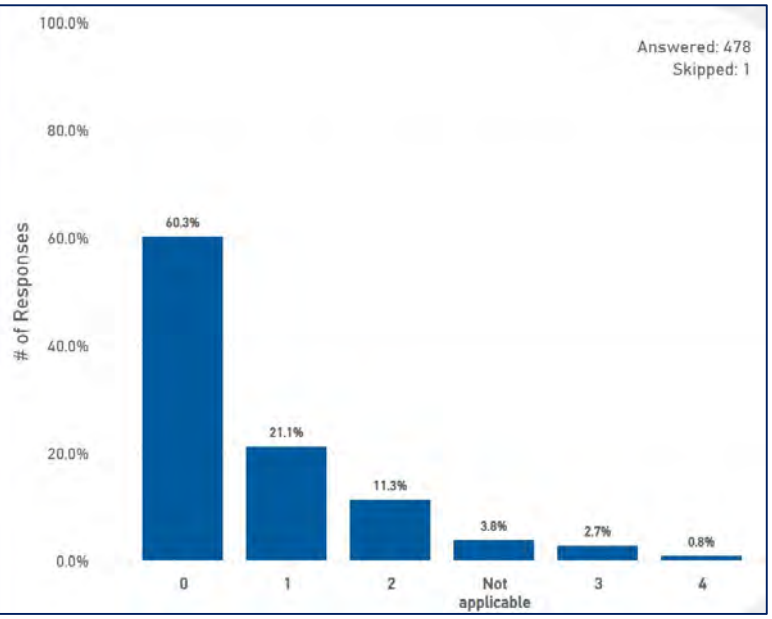
All Responses



15. Provide the number of clerks/cashiers that work during your shift.

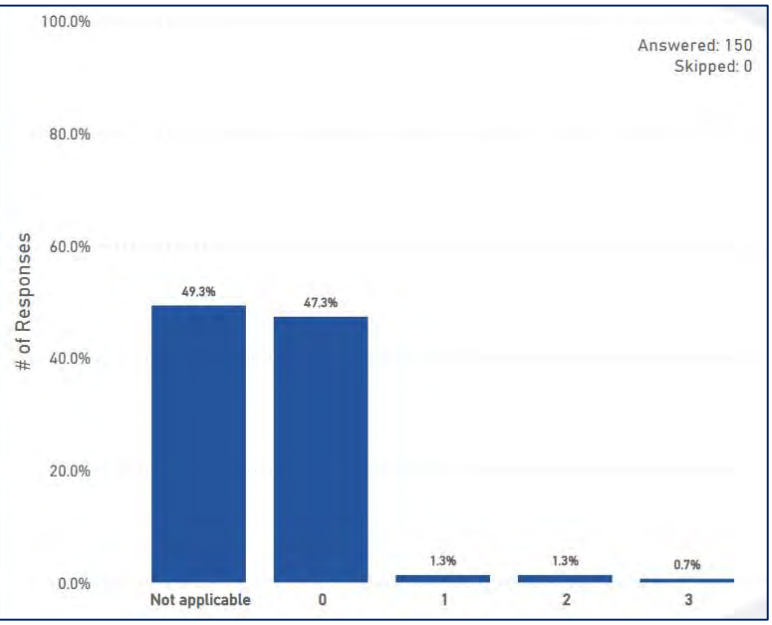
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
0	288	60.3%
1	101	21.1%
2	54	11.3%
Not applicable	18	3.8%
3	13	2.7%
4	4	0.8%
Total	**478**	**100.0%**



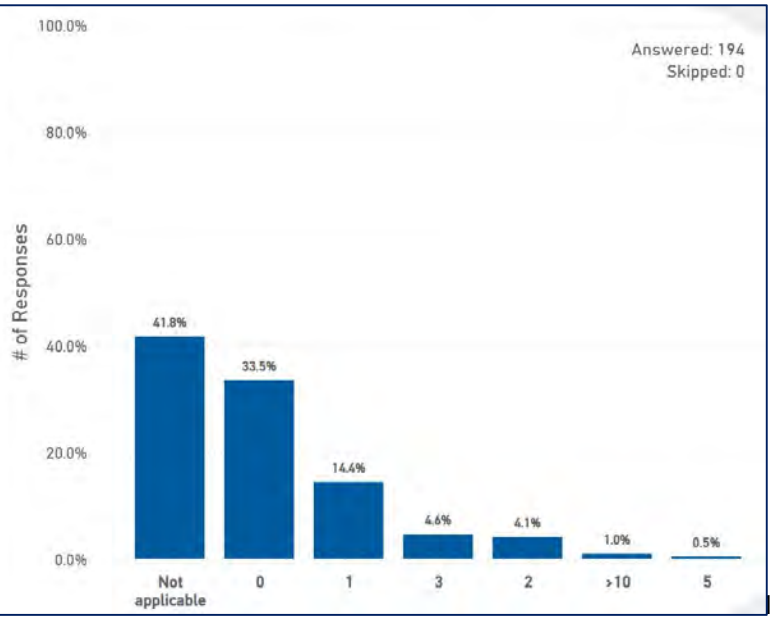
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Not applicable	74	49.3%
0	71	47.3%
1	2	1.3%
2	2	1.3%
3	1	0.7%
Total	**150**	**100.0%**



Other

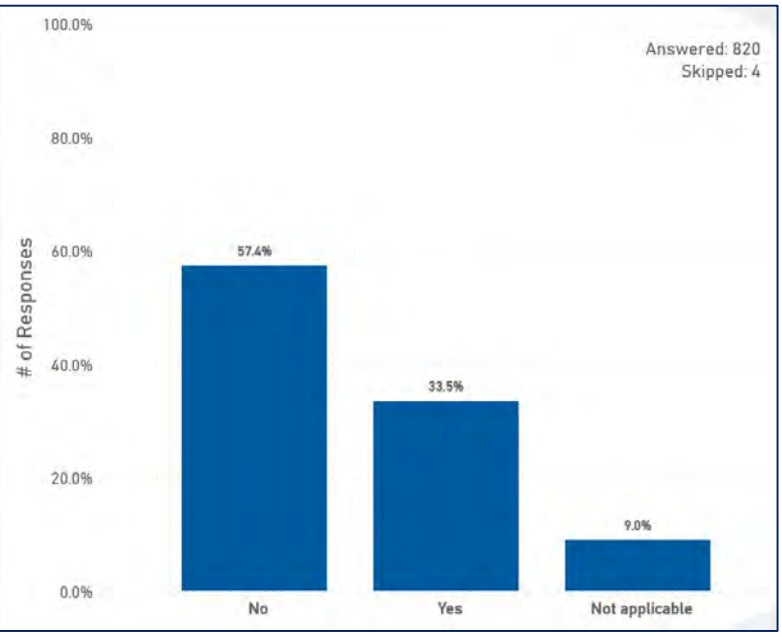
Survey Responses	# Responses	% Responses
Not applicable	81	41.8%
0	65	33.5%
1	28	14.4%
3	9	4.6%
2	8	4.1%
>10	2	1.0%
5	1	0.5%
Total	**194**	**100.0%**



16. Do you believe your primary practice setting is sufficiently staffed to meet the demands of the pharmacy while meeting patient care and safety standards?

Survey Responses	# Responses	% Responses
No	471	57.4%
Yes	275	33.5%
Not applicable	74	9.0%
Total	**820**	**100.0%**

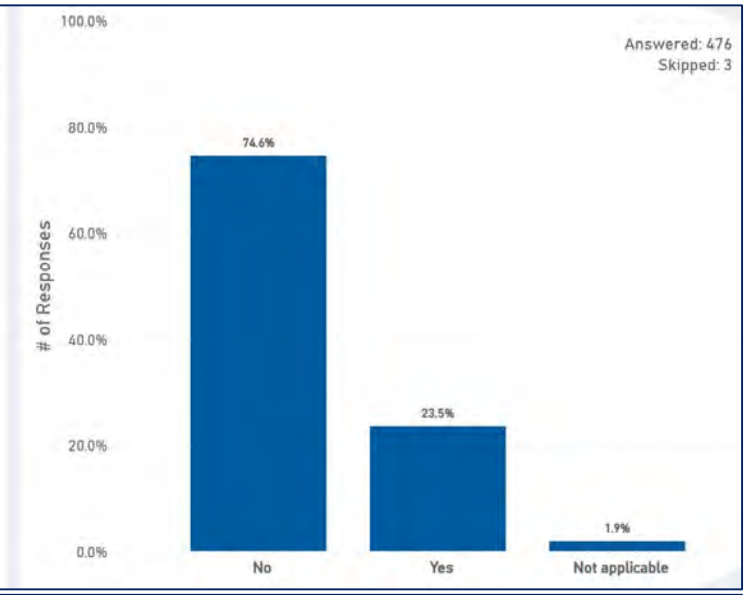
All Responses



16. Do you believe your primary practice setting is sufficiently staffed to meet the demands of the pharmacy while meeting patient care and safety standards?

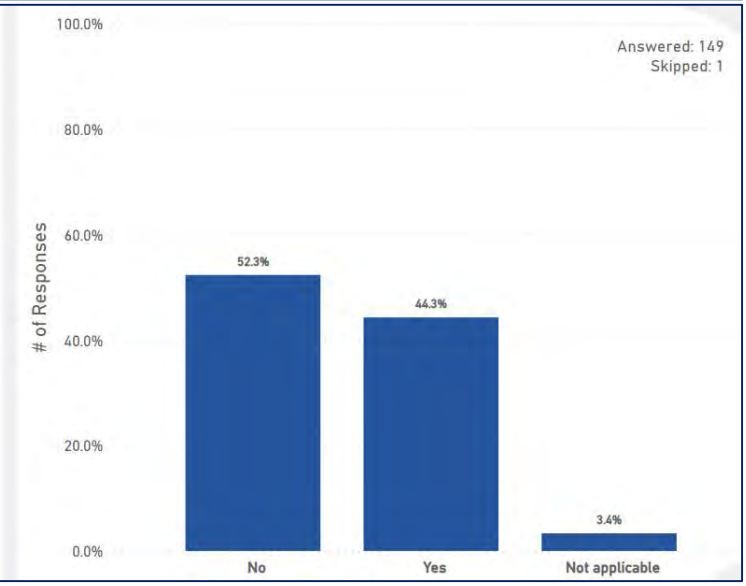
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
No	355	74.6%
Yes	112	23.5%
Not applicable	9	1.9%
Total	**476**	**100.0%**



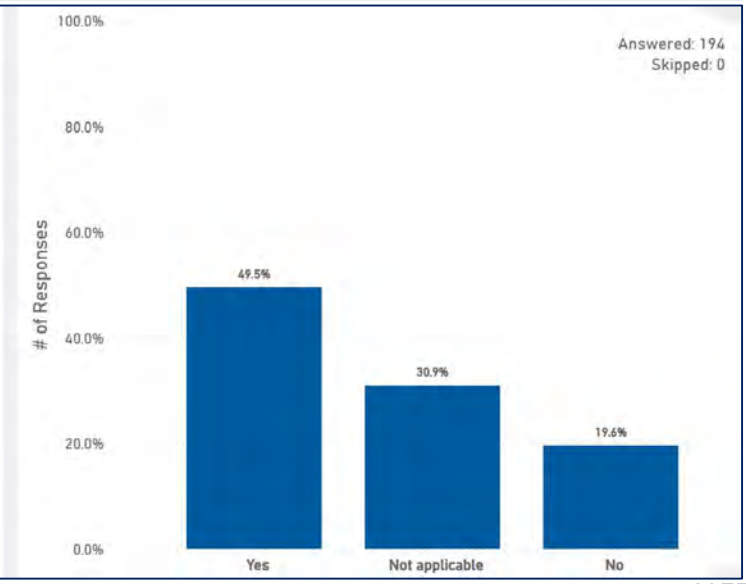
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
No	78	52.3%
Yes	66	44.3%
Not applicable	5	3.4%
Total	**149**	**100.0%**



Other

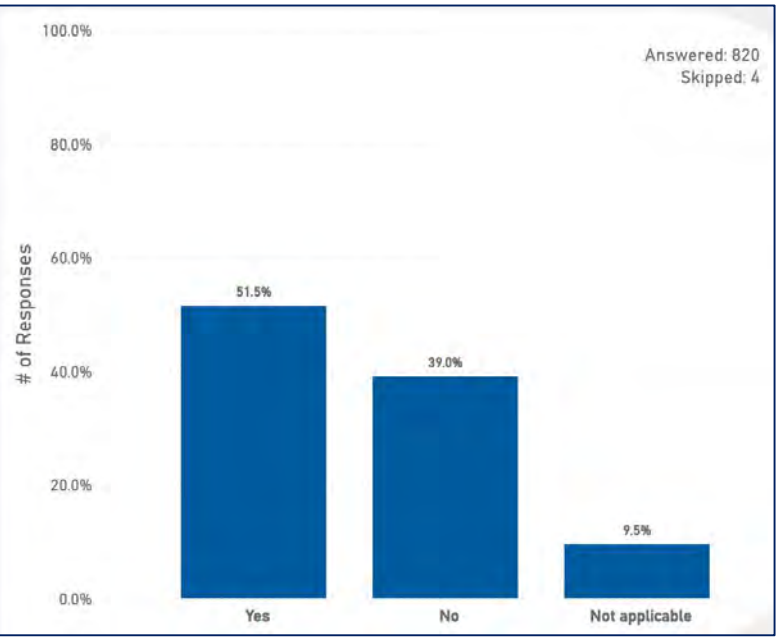
Survey Responses	# Responses	% Responses
Yes	96	49.5%
Not applicable	60	30.9%
No	38	19.6%
Total	**194**	**100.0%**



17. Do you believe the current staffing in your primary practice setting poses a risk to patient safety?

Survey Responses	# Responses	% Responses
Yes	422	51.5%
No	320	39.0%
Not applicable	78	9.5%
Total	**820**	**100.0%**

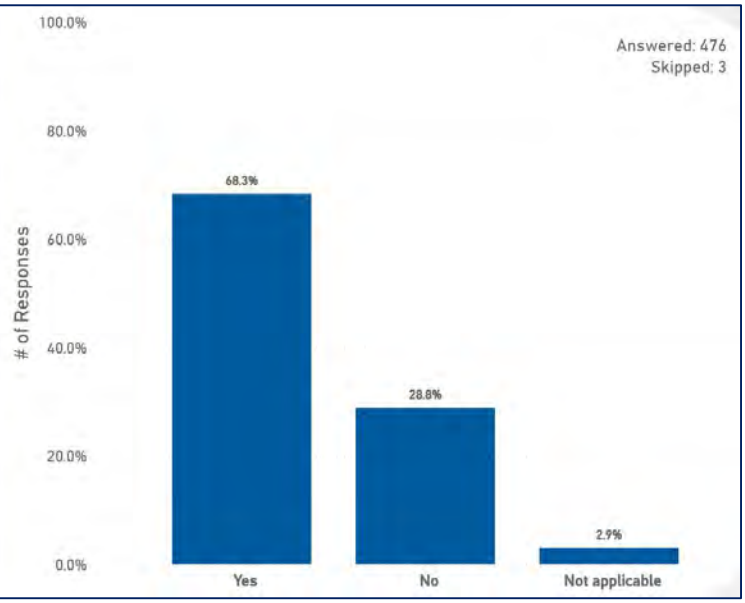
All Responses



17. Do you believe the current staffing in your primary practice setting poses a risk to patient safety?

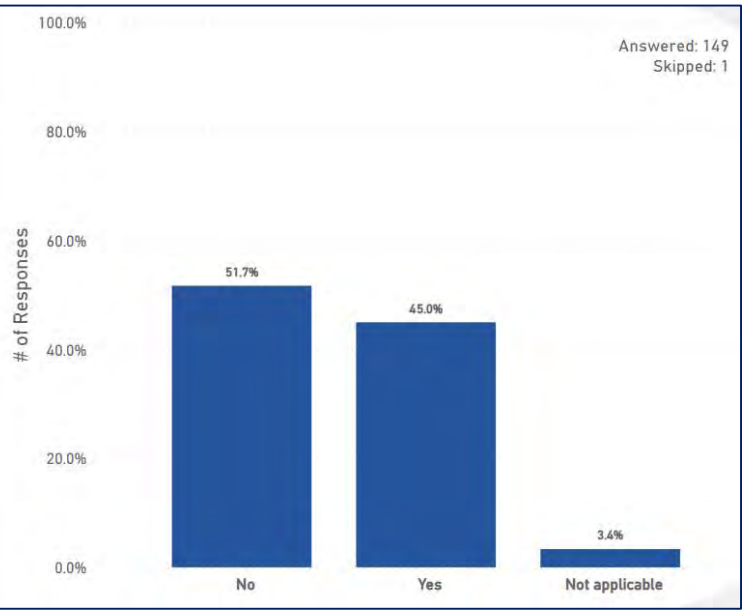
Survey Responses	# Responses	% Responses
Yes	325	68.3%
No	137	28.8%
Not applicable	14	2.9%
Total	**476**	**100.0%**

Retail Chain Pharmacist



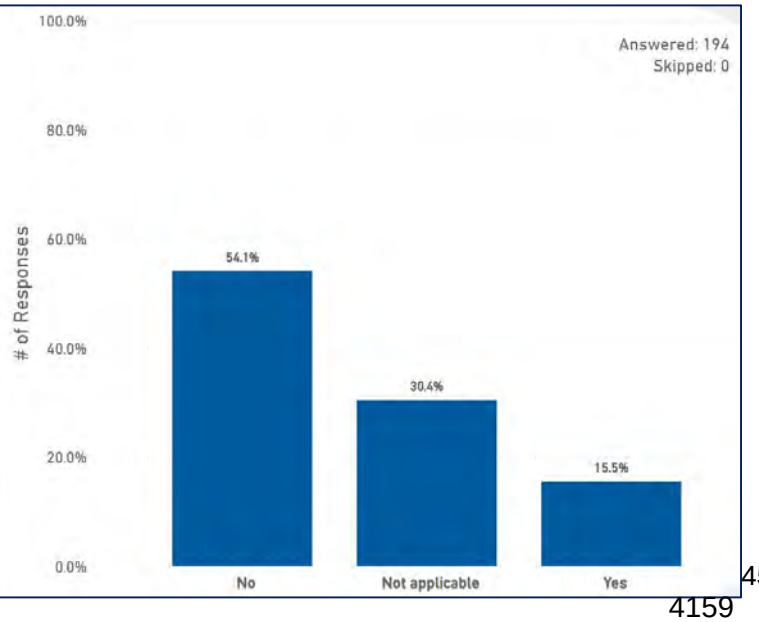
Survey Responses	# Responses	% Responses
No	77	51.7%
Yes	67	45.0%
Not applicable	5	3.4%
Total	**149**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
No	105	54.1%
Not applicable	59	30.4%
Yes	30	15.5%
Total	**194**	**100.0%**

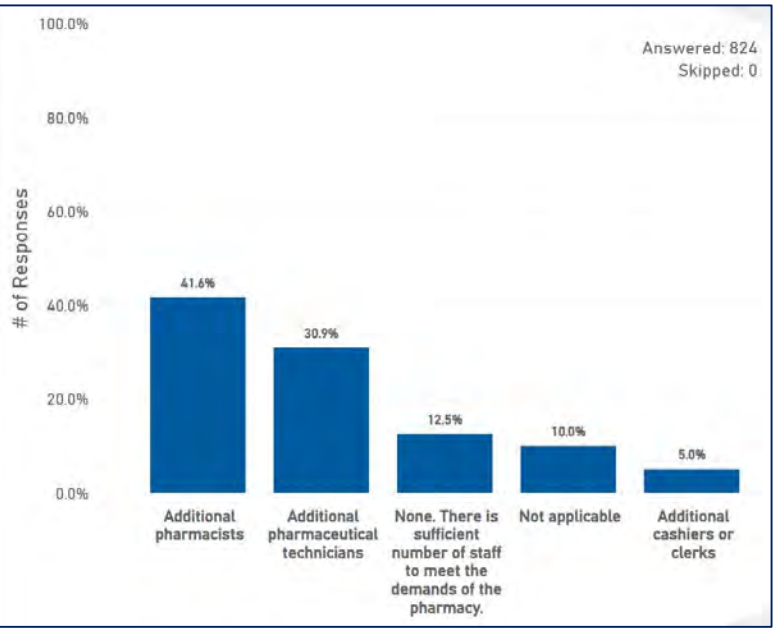
Other



18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?

Survey Responses	# Responses	% Responses
Additional pharmacists	343	41.6%
Additional pharmaceutical technicians	255	30.9%
None. There is sufficient number of staff to meet the demands of the pharmacy.	103	12.5%
Not applicable	82	10.0%
Additional cashiers or clerks	41	5.0%
Total	**824**	**100.0%**

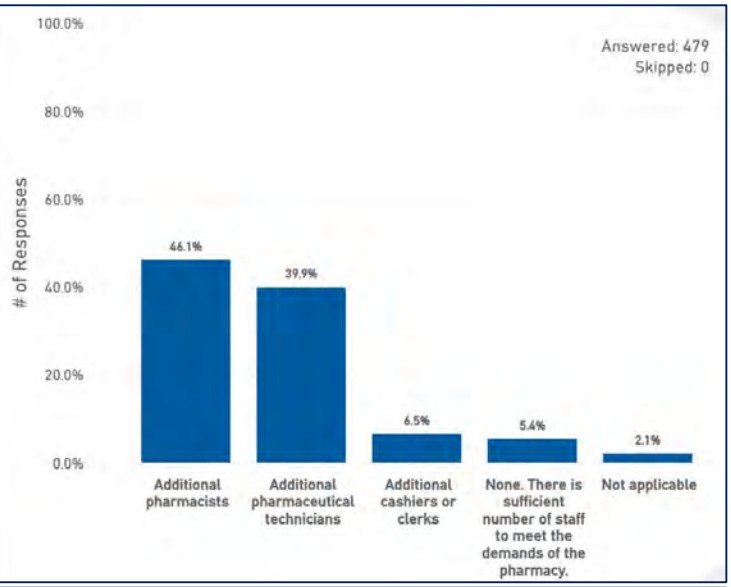
All Responses



18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?

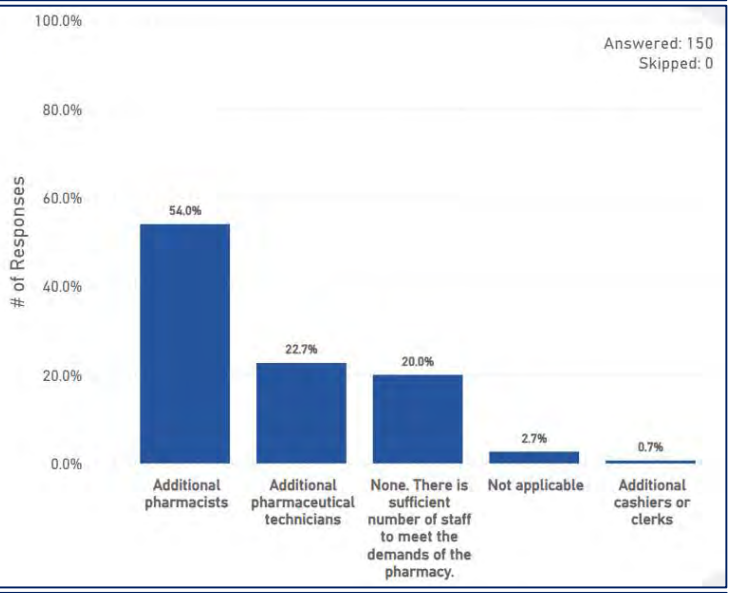
Survey Responses	# Responses	% Responses
Additional pharmacists	221	46.1%
Additional pharmaceutical technicians	191	39.9%
Additional cashiers or clerks	31	6.5%
None. There is sufficient number of staff to meet the demands of the pharmacy.	26	5.4%
Not applicable	10	2.1%
Total	**479**	**100.0%**

Retail Chain Pharmacist



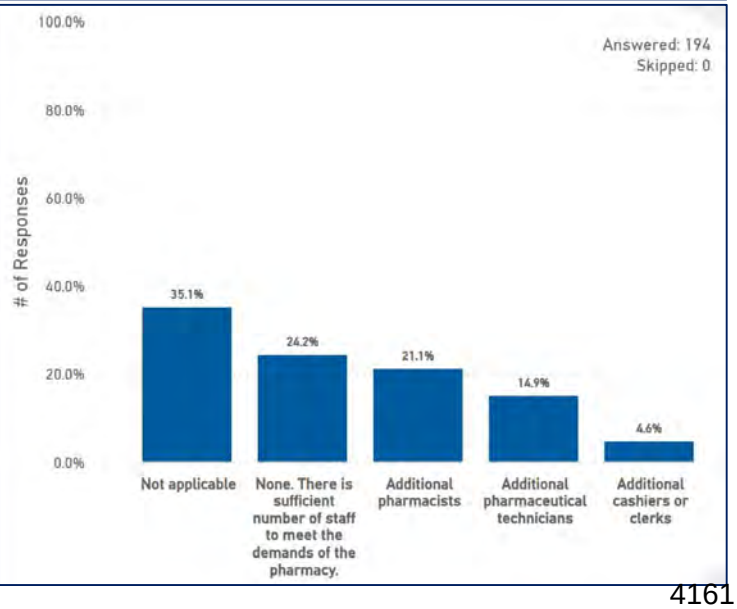
Survey Responses	# Responses	% Responses
Additional pharmacists	81	54.0%
Additional pharmaceutical technicians	34	22.7%
None. There is sufficient number of staff to meet the demands of the pharmacy.	30	20.0%
Not applicable	4	2.7%
Additional cashiers or clerks	1	0.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	68	35.1%
None. There is sufficient number of staff to meet the demands of the pharmacy.	47	24.2%
Additional pharmacists	41	21.1%
Additional pharmaceutical technicians	29	14.9%
Additional cashiers or clerks	9	4.6%
Total	**194**	**100.0%**

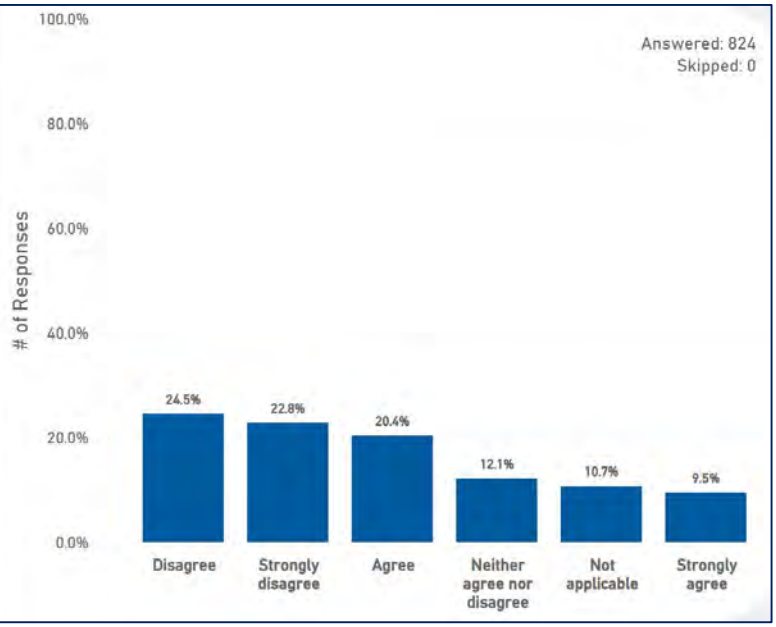
Other



19. I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care.

Survey Responses	# Responses	% Responses
Disagree	202	24.5%
Strongly disagree	188	22.8%
Agree	168	20.4%
Neither agree nor disagree	100	12.1%
Not applicable	88	10.7%
Strongly agree	78	9.5%
Total	**824**	**100.0%**

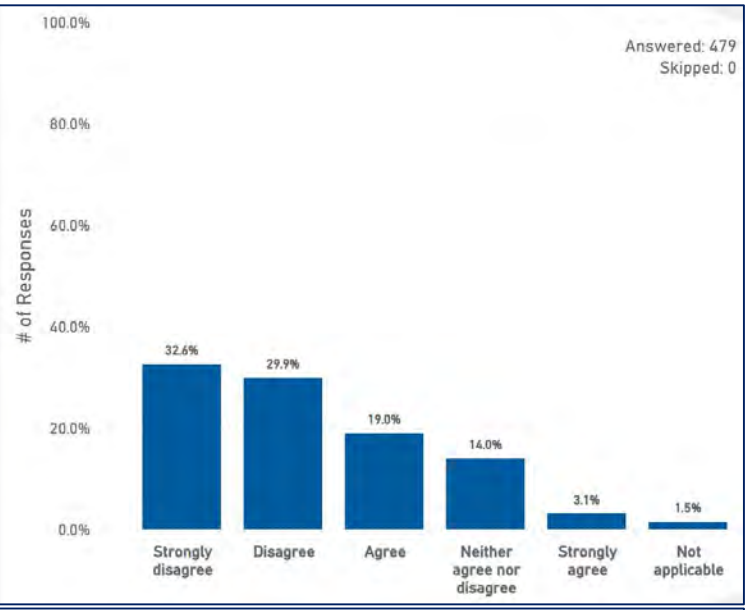
All Responses



19. I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care.

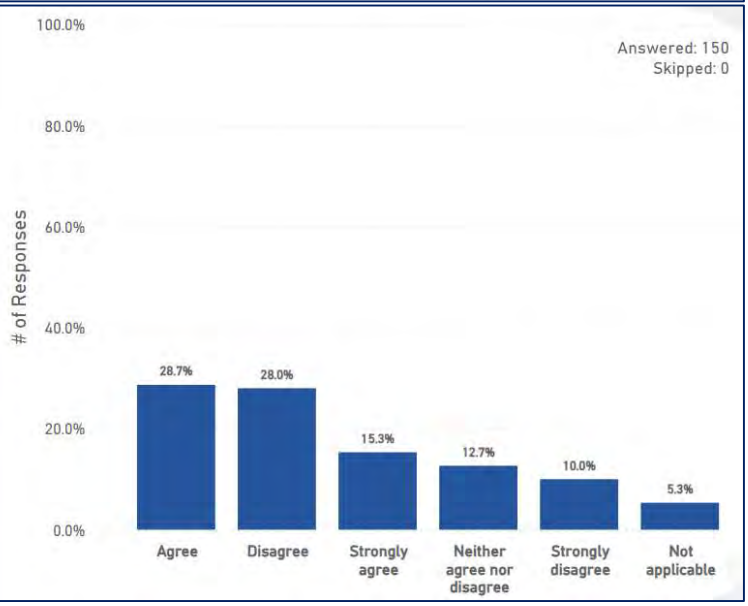
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Strongly disagree	156	32.6%
Disagree	143	29.9%
Agree	91	19.0%
Neither agree nor disagree	67	14.0%
Strongly agree	15	3.1%
Not applicable	7	1.5%
Total	**479**	**100.0%**



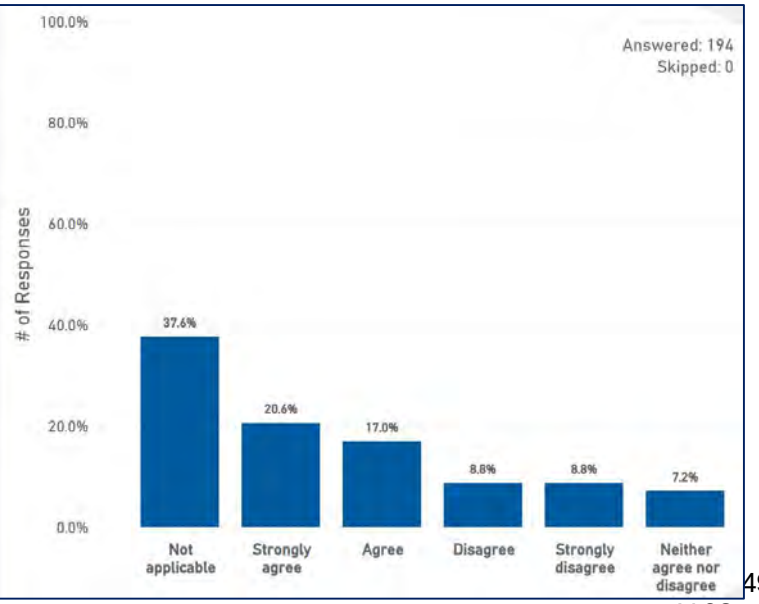
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Agree	43	28.7%
Disagree	42	28.0%
Strongly agree	23	15.3%
Neither agree nor disagree	19	12.7%
Strongly disagree	15	10.0%
Not applicable	8	5.3%
Total	**150**	**100.0%**



Other

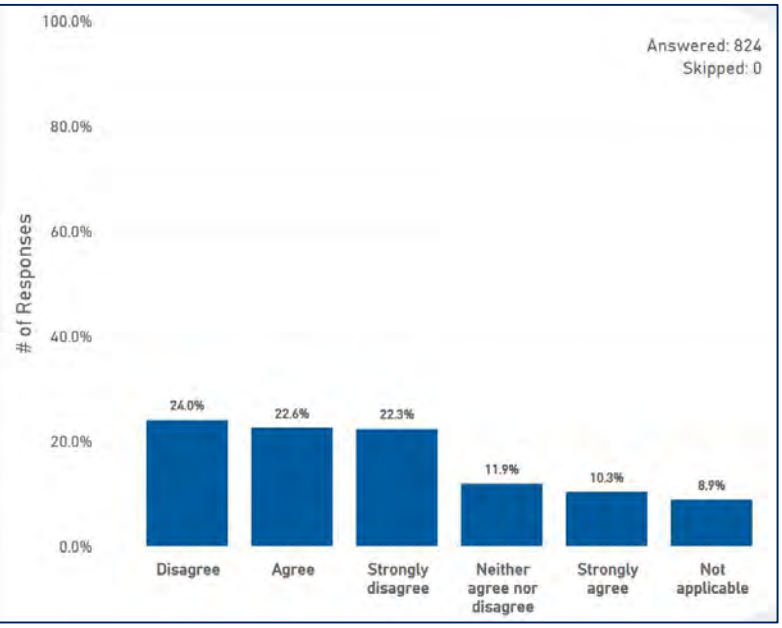
Survey Responses	# Responses	% Responses
Not applicable	73	37.6%
Strongly agree	40	20.6%
Agree	33	17.0%
Disagree	17	8.8%
Strongly disagree	17	8.8%
Neither agree nor disagree	14	7.2%
Total	**194**	**100.0%**



20. I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care.

Survey Responses	# Responses	% Responses
Disagree	198	24.0%
Agree	186	22.6%
Strongly disagree	184	22.3%
Neither agree nor disagree	98	11.9%
Strongly agree	85	10.3%
Not applicable	73	8.9%
Total	**824**	**100.0%**

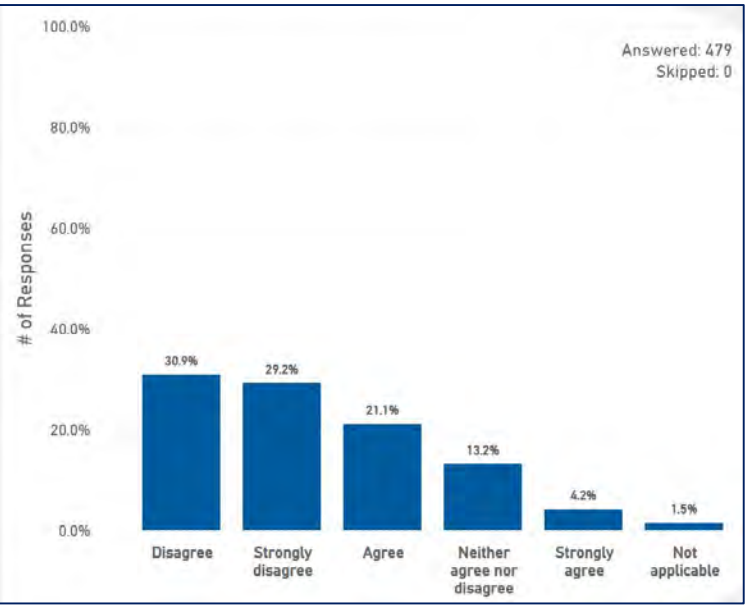
All Responses



20. I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care.

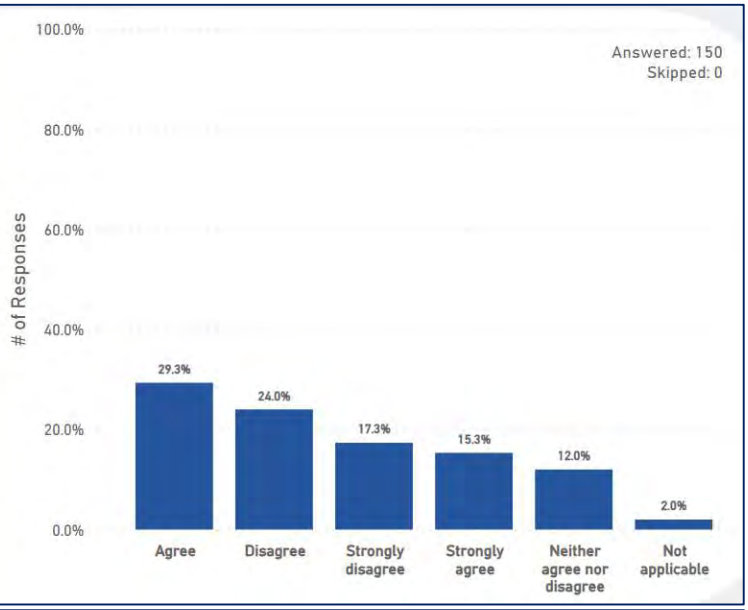
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Disagree	148	30.9%
Strongly disagree	140	29.2%
Agree	101	21.1%
Neither agree nor disagree	63	13.2%
Strongly agree	20	4.2%
Not applicable	7	1.5%
Total	**479**	**100.0%**



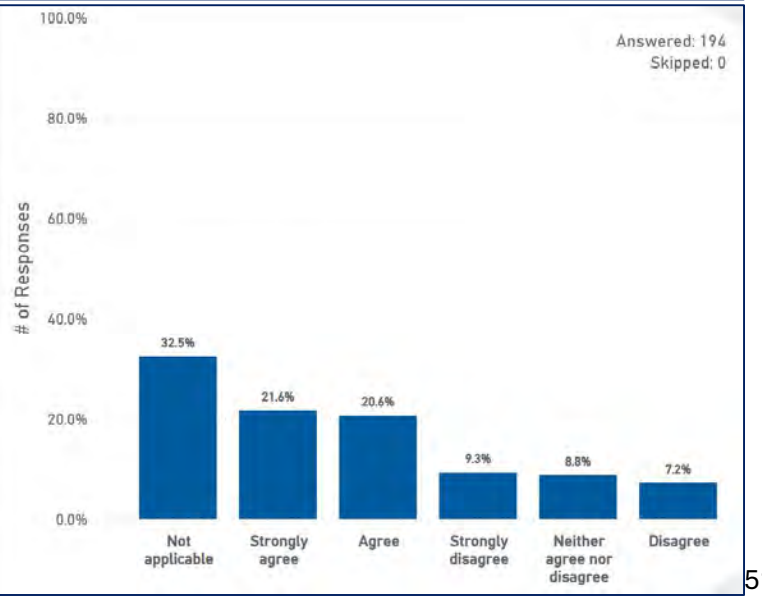
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Agree	44	29.3%
Disagree	36	24.0%
Strongly disagree	26	17.3%
Strongly agree	23	15.3%
Neither agree nor disagree	18	12.0%
Not applicable	3	2.0%
Total	**150**	**100.0%**



Other

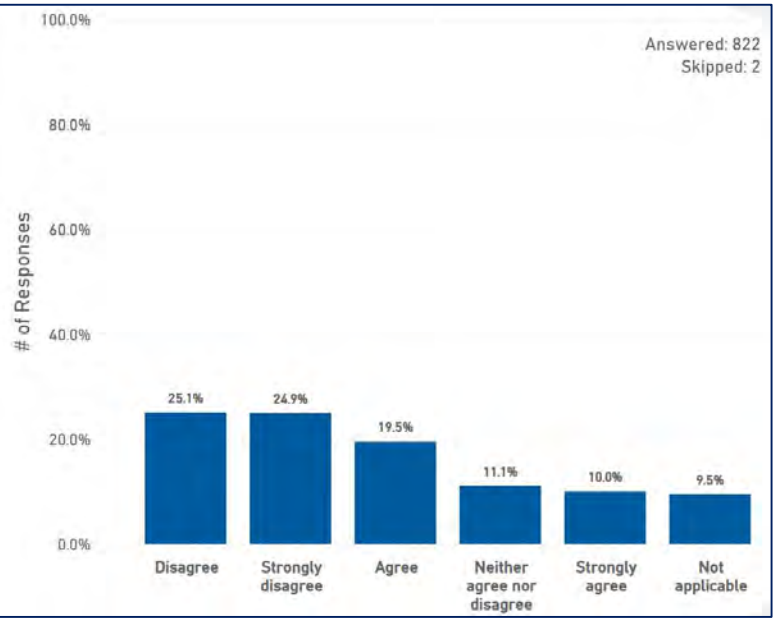
Survey Responses	# Responses	% Responses
Not applicable	63	32.5%
Strongly agree	42	21.6%
Agree	40	20.6%
Strongly disagree	18	9.3%
Neither agree nor disagree	17	8.8%
Disagree	14	7.2%
Total	**194**	**100.0%**



21. I feel that staffing at my pharmacy is adequate to prevent delays in patients receiving medications in a timely manner.

Survey Responses	# Responses	% Responses
Disagree	206	25.1%
Strongly disagree	205	24.9%
Agree	160	19.5%
Neither agree nor disagree	91	11.1%
Strongly agree	82	10.0%
Not applicable	78	9.5%
Total	**822**	**100.0%**

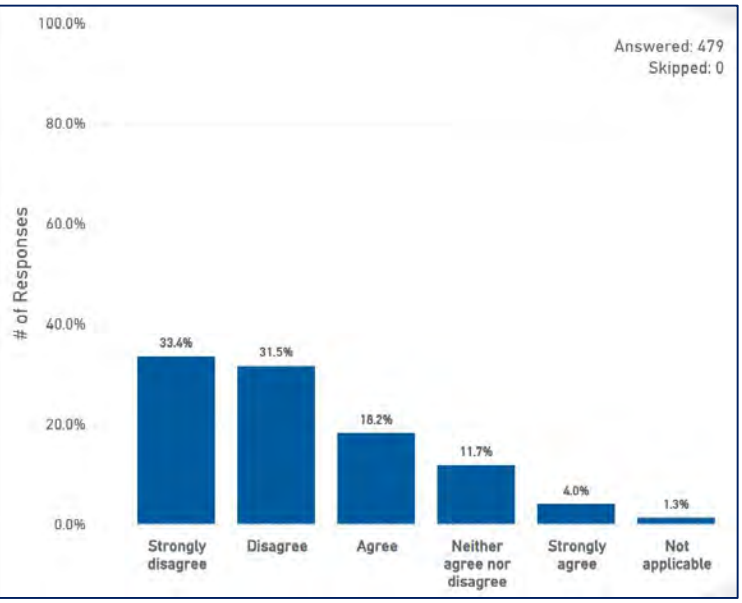
All Responses



21. I feel that staffing at my pharmacy is adequate to prevent delays in patients receiving medications in a timely manner.

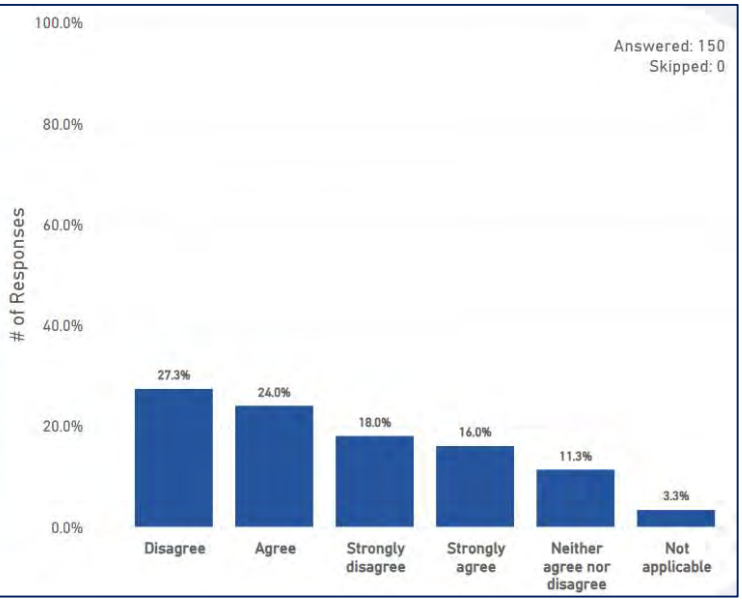
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Strongly disagree	160	33.4%
Disagree	151	31.5%
Agree	87	18.2%
Neither agree nor disagree	56	11.7%
Strongly agree	19	4.0%
Not applicable	6	1.3%
Total	**479**	**100.0%**



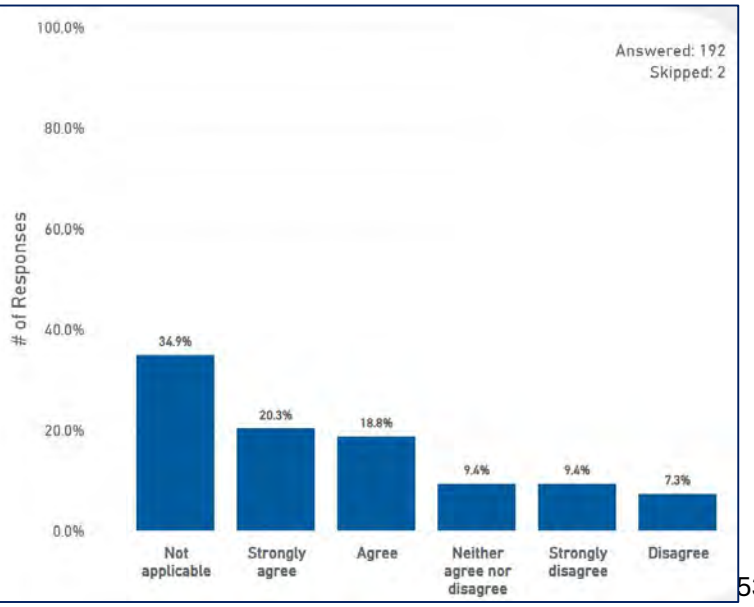
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Disagree	41	27.3%
Agree	36	24.0%
Strongly disagree	27	18.0%
Strongly agree	24	16.0%
Neither agree nor disagree	17	11.3%
Not applicable	5	3.3%
Total	**150**	**100.0%**



Other

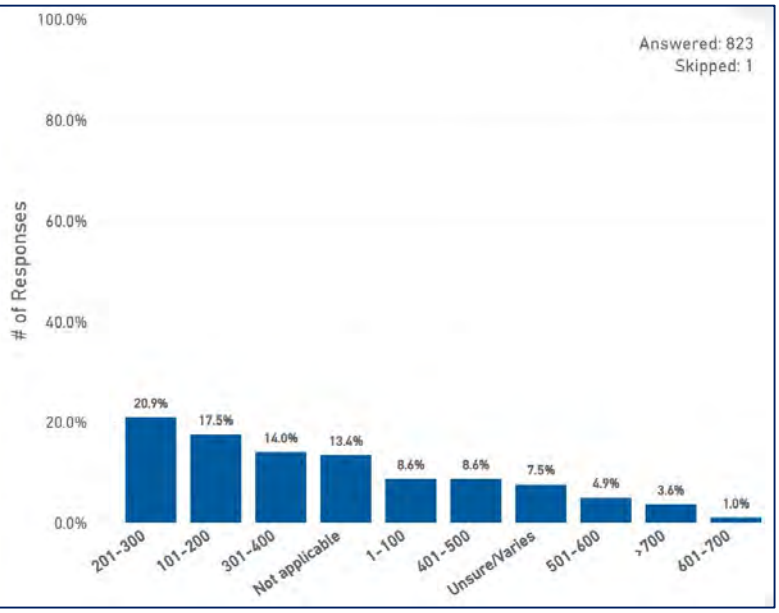
Survey Responses	# Responses	% Responses
Not applicable	67	34.9%
Strongly agree	39	20.3%
Agree	36	18.8%
Neither agree nor disagree	18	9.4%
Strongly disagree	18	9.4%
Disagree	14	7.3%
Total	**192**	**100.0%**



22. On average, what number of prescriptions or chart orders do YOU process during your shift?

Survey Responses	# Responses	% Responses
201-300	172	20.9%
101-200	144	17.5%
301-400	115	14.0%
Not applicable	110	13.4%
1-100	71	8.6%
401-500	71	8.6%
Unsure/Varies	62	7.5%
501-600	40	4.9%
>700	30	3.6%
601-700	8	1.0%
Total	**823**	**100.0%**

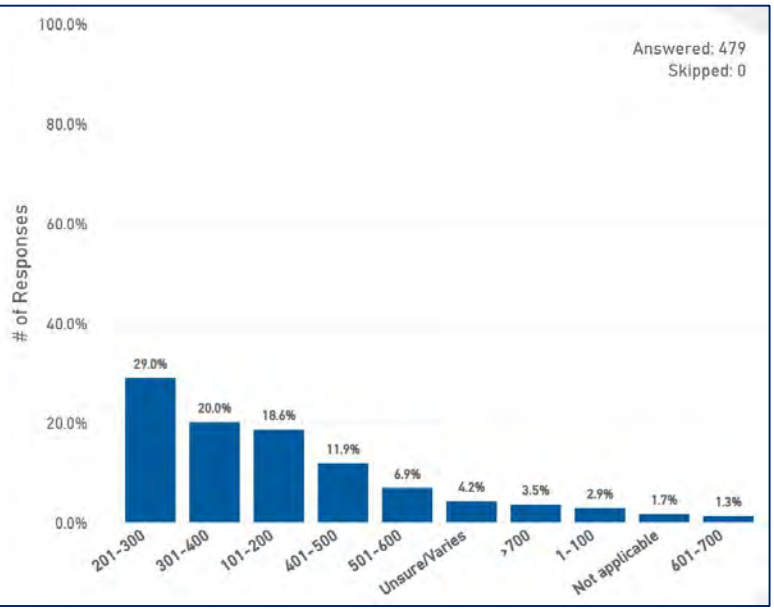
All Responses



22. On average, what number of prescriptions or chart orders do YOU process during your shift?

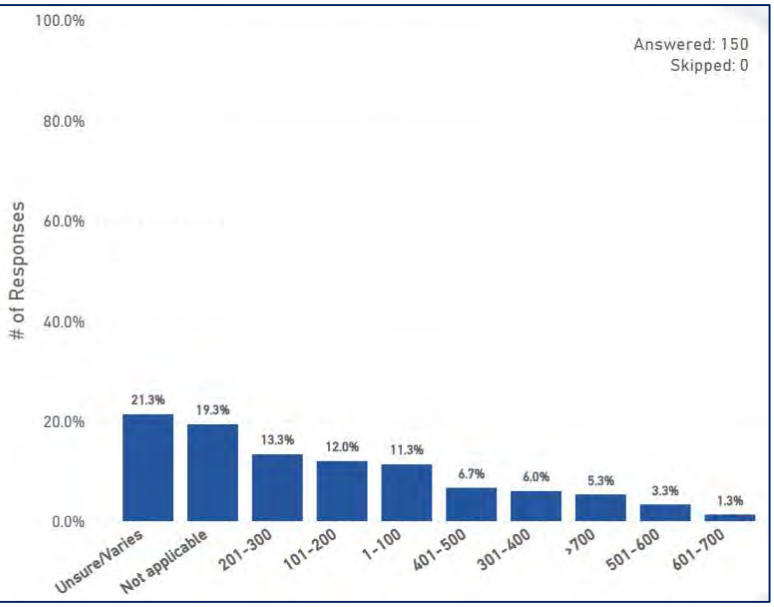
Survey Responses	# Responses	% Responses
201-300	139	29.0%
301-400	96	20.0%
101-200	89	18.6%
401-500	57	11.9%
501-600	33	6.9%
Unsure/Varies	20	4.2%
>700	17	3.5%
1-100	14	2.9%
Not applicable	8	1.7%
601-700	6	1.3%
Total	**479**	**100.0%**

Retail Chain Pharmacist



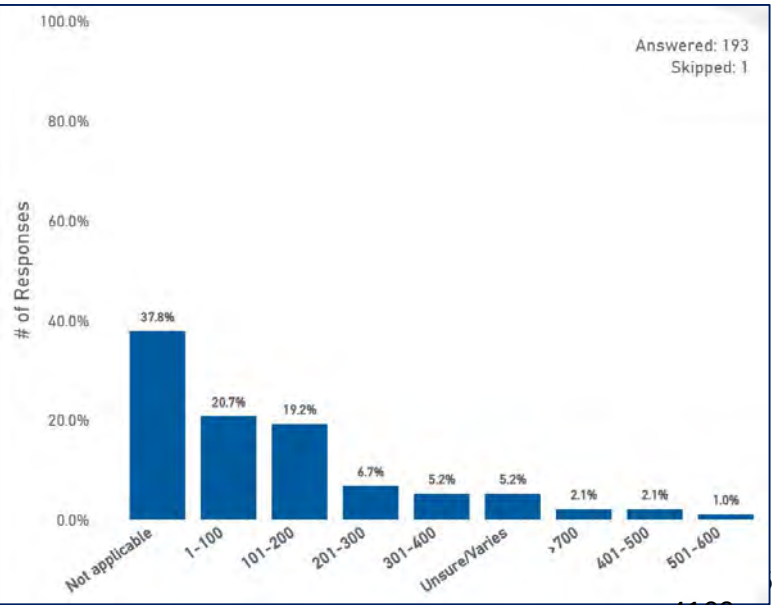
Survey Responses	# Responses	% Responses
Unsure/Varies	32	21.3%
Not applicable	29	19.3%
201-300	20	13.3%
101-200	18	12.0%
1-100	17	11.3%
401-500	10	6.7%
301-400	9	6.0%
>700	8	5.3%
501-600	5	3.3%
601-700	2	1.3%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	73	37.8%
1-100	40	20.7%
101-200	37	19.2%
201-300	13	6.7%
301-400	10	5.2%
Unsure/Varies	10	5.2%
>700	4	2.1%
401-500	4	2.1%
501-600	2	1.0%
Total	**193**	**100.0%**

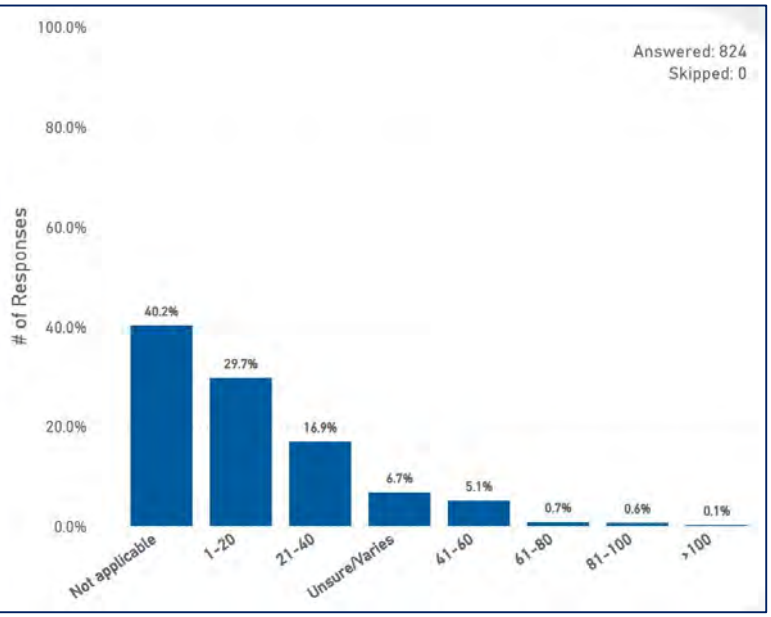
Other



23. On average, how many vaccines do YOU administer or supervise the administration of during your shift?

Survey Responses	# Responses	% Responses
Not applicable	331	40.2%
1-20	245	29.7%
21-40	139	16.9%
Unsure/Varies	55	6.7%
41-60	42	5.1%
61-80	6	0.7%
81-100	5	0.6%
>100	1	0.1%
Total	**824**	**100.0%**

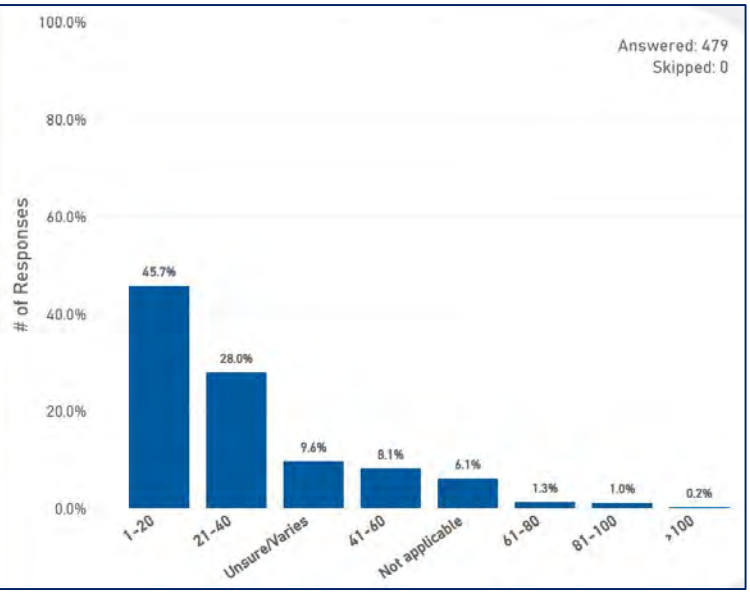
All Responses



23. On average, how many vaccines do YOU administer or supervise the administration of during your shift?

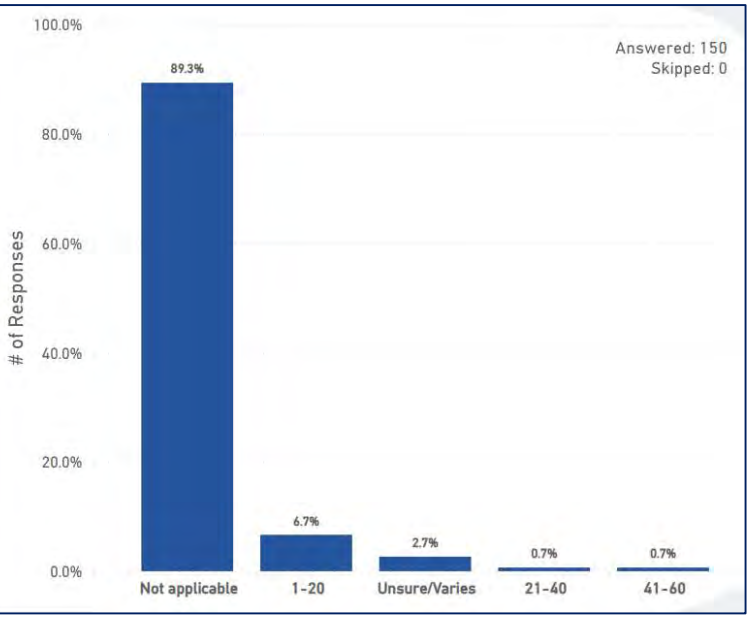
Survey Responses	# Responses	% Responses
1-20	219	45.7%
21-40	134	28.0%
Unsure/Varies	46	9.6%
41-60	39	8.1%
Not applicable	29	6.1%
61-80	6	1.3%
81-100	5	1.0%
>100	1	0.2%
Total	**479**	**100.0%**

Retail Chain Pharmacist



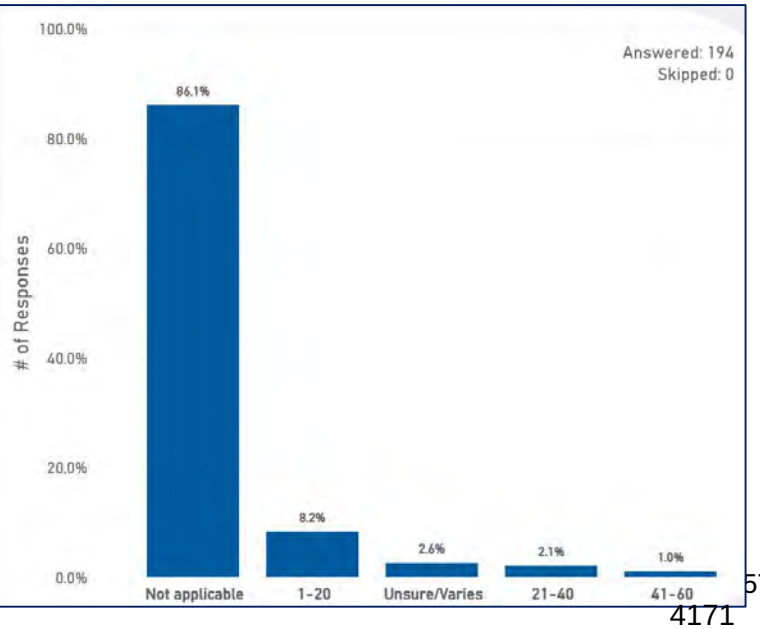
Survey Responses	# Responses	% Responses
Not applicable	134	89.3%
1-20	10	6.7%
Unsure/Varies	4	2.7%
21-40	1	0.7%
41-60	1	0.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	167	86.1%
1-20	16	8.2%
Unsure/Varies	5	2.6%
21-40	4	2.1%
41-60	2	1.0%
Total	**194**	**100.0%**

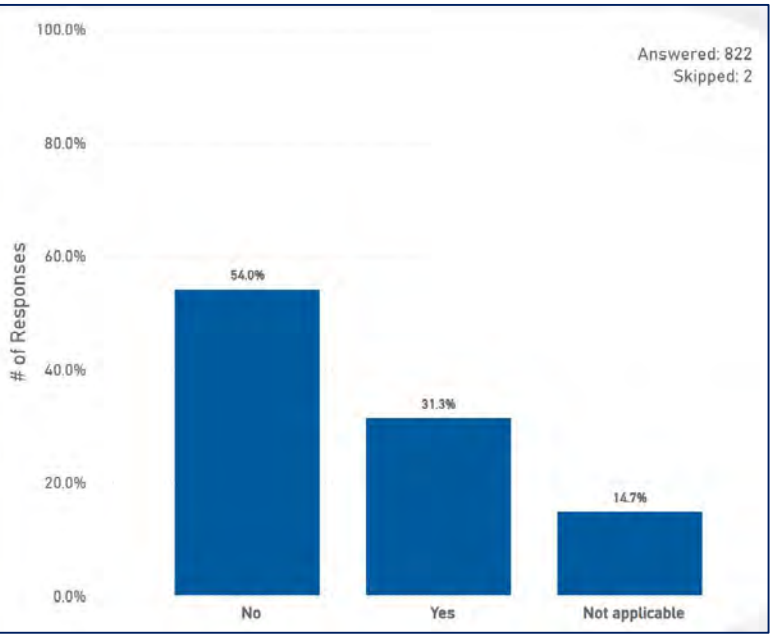
Other



24. Does your primary practice setting perform sterile or non-sterile compounding?

Survey Responses	# Responses	% Responses
No	444	54.0%
Yes	257	31.3%
Not applicable	121	14.7%
Total	**822**	**100.0%**

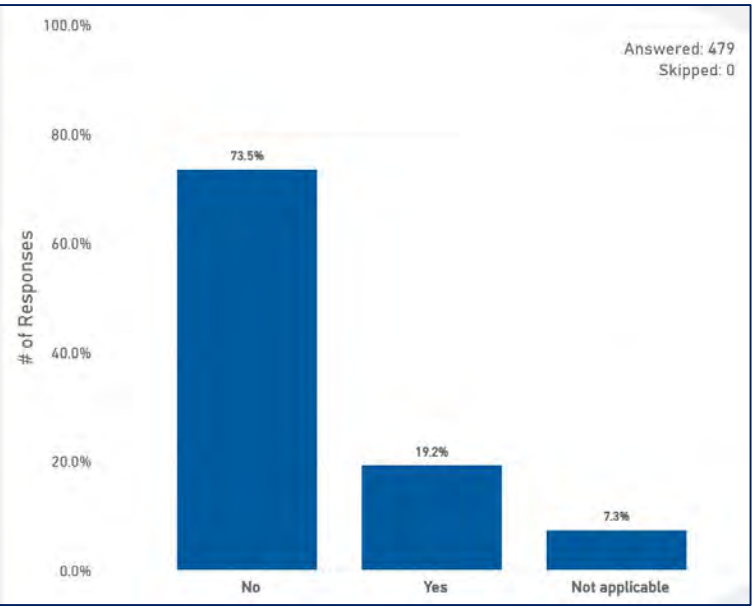
All Responses



24. Does your primary practice setting perform sterile or non-sterile compounding?

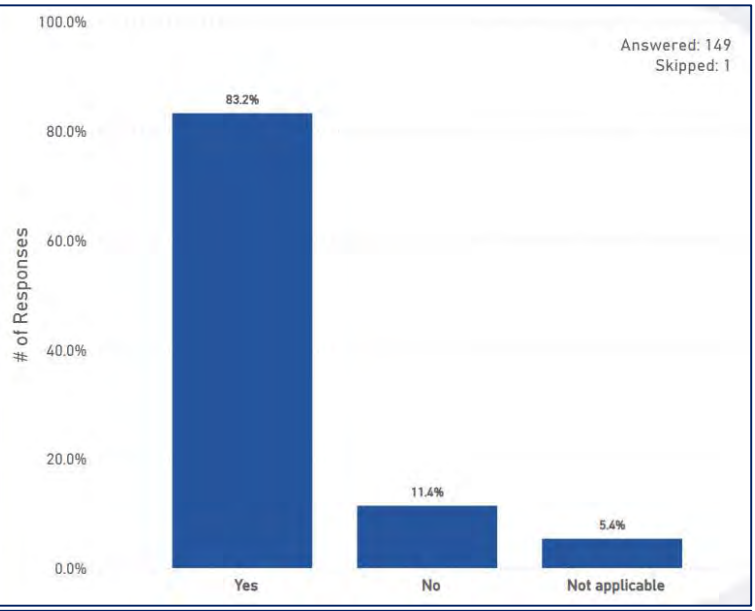
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
No	352	73.5%
Yes	92	19.2%
Not applicable	35	7.3%
Total	**479**	**100.0%**



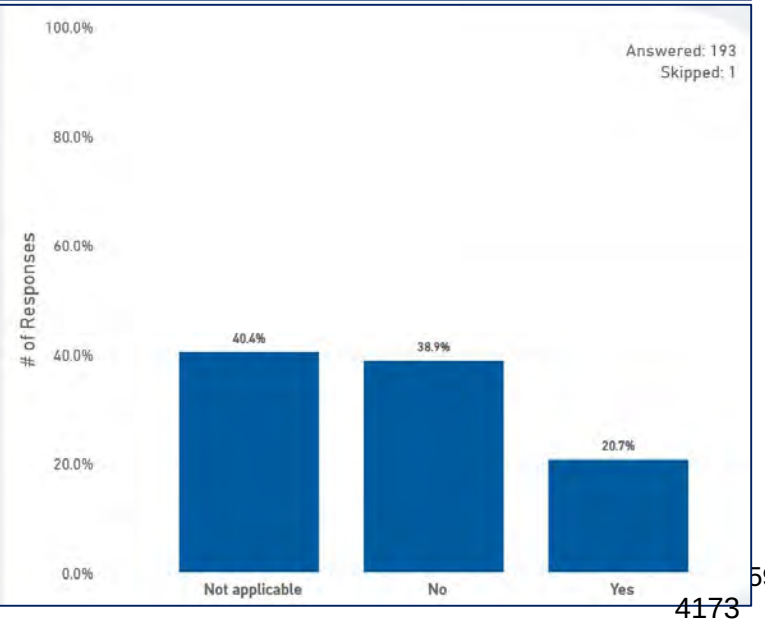
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	124	83.2%
No	17	11.4%
Not applicable	8	5.4%
Total	**149**	**100.0%**



Other

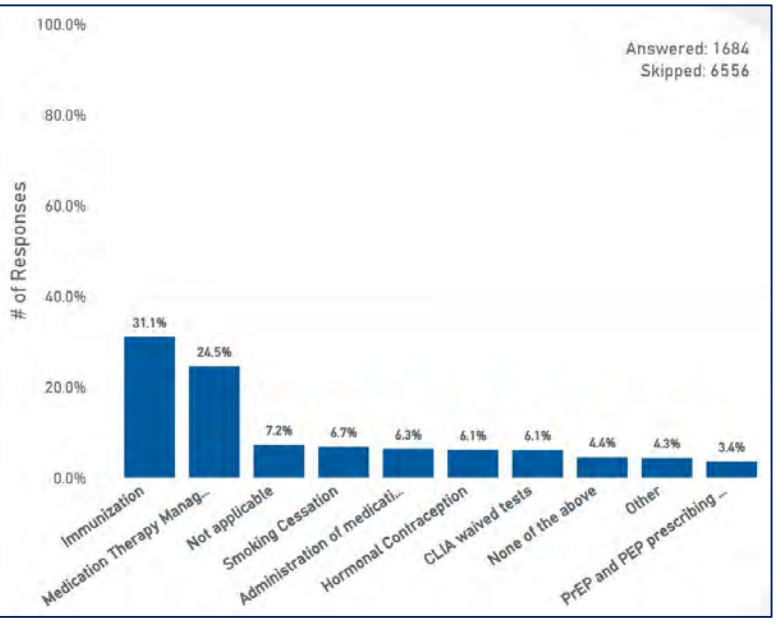
Survey Responses	# Responses	% Responses
Not applicable	78	40.4%
No	75	38.9%
Yes	40	20.7%
Total	**193**	**100.0%**



25. Which of the following services are provided at your primary practice setting?

Survey Responses	# Responses	% Responses
Immunization	523	31.1%
Medication Therapy Management	412	24.5%
Not applicable	121	7.2%
Smoking Cessation	113	6.7%
Administration of medications and biologics	106	6.3%
Hormonal Contraception	103	6.1%
CLIA waived tests	102	6.1%
None of the above	74	4.4%
Other	72	4.3%
PrEP and PEP prescribing and dispensing	58	3.4%
Total	**1684**	**100.0%**

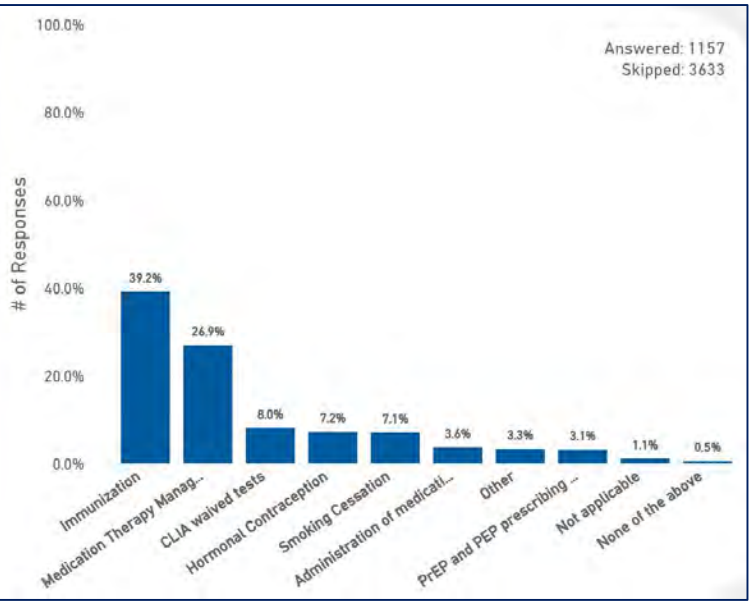
All Responses



25. Which of the following services are provided at your primary practice setting?

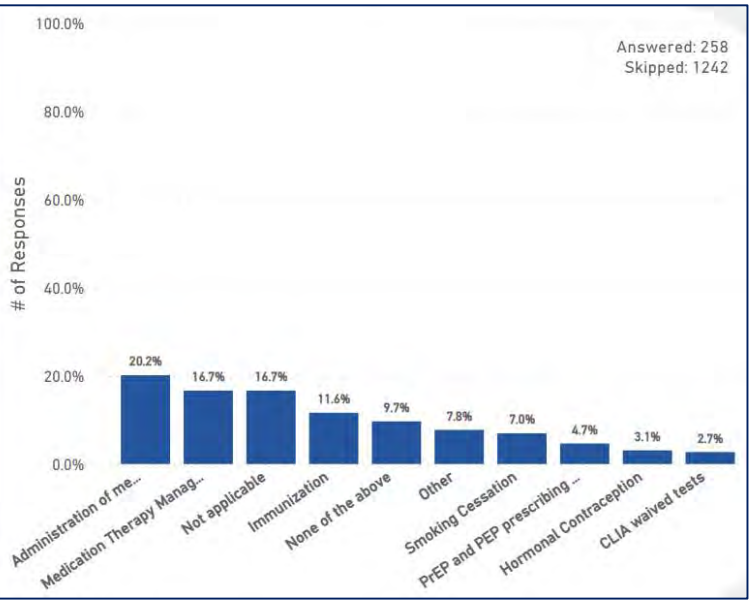
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Immunization	453	39.2%
Medication Therapy Management	311	26.9%
CLIA waived tests	93	8.0%
Hormonal Contraception	83	7.2%
Smoking Cessation	82	7.1%
Administration of medications and biologics	42	3.6%
Other	38	3.3%
PrEP and PEP prescribing and dispensing	36	3.1%
Not applicable	13	1.1%
None of the above	6	0.5%
Total	**1157**	**100.0%**



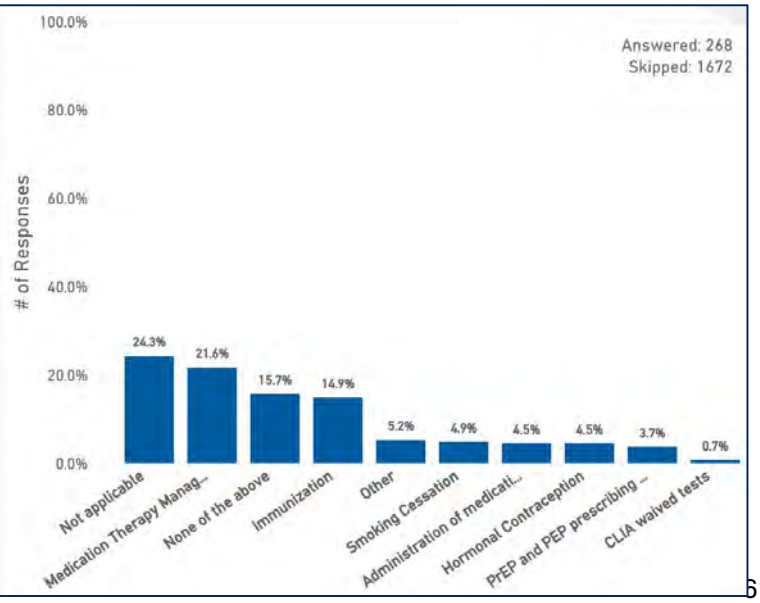
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Administration of medications and biologics	52	20.2%
Medication Therapy Management	43	16.7%
Not applicable	43	16.7%
Immunization	30	11.6%
None of the above	25	9.7%
Other	20	7.8%
Smoking Cessation	18	7.0%
PrEP and PEP prescribing and dispensing	12	4.7%
Hormonal Contraception	8	3.1%
CLIA waived tests	7	2.7%
Total	**258**	**100.0%**



Other

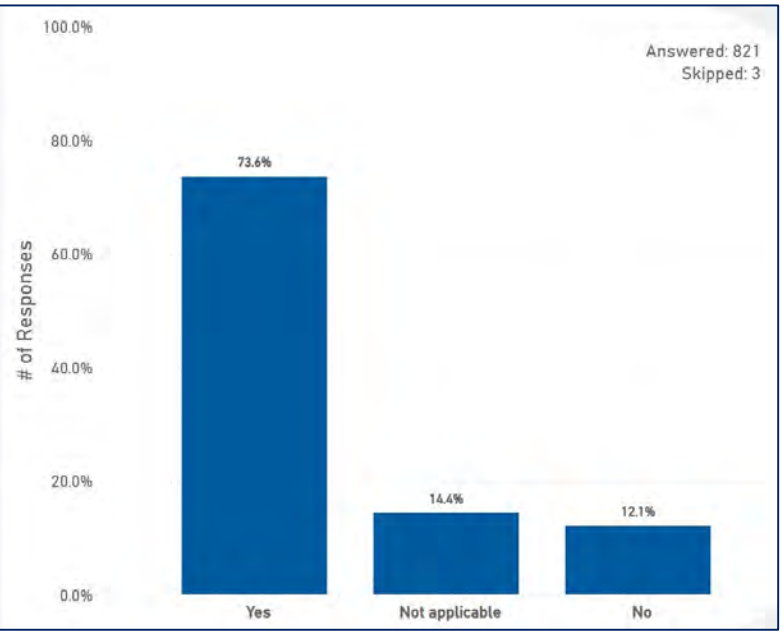
Survey Responses	# Responses	% Responses
Not applicable	65	24.3%
Medication Therapy Management	58	21.6%
None of the above	42	15.7%
Immunization	40	14.9%
Other	14	5.2%
Smoking Cessation	13	4.9%
Administration of medications and biologics	12	4.5%
Hormonal Contraception	12	4.5%
PrEP and PEP prescribing and dispensing	10	3.7%
CLIA waived tests	2	0.7%
Total	**268**	**100.0%**



26. Does your employer require you to complete non-dispensing related services, such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects?

Survey Responses	# Responses	% Responses
Yes	604	73.6%
Not applicable	118	14.4%
No	99	12.1%
Total	**821**	**100.0%**

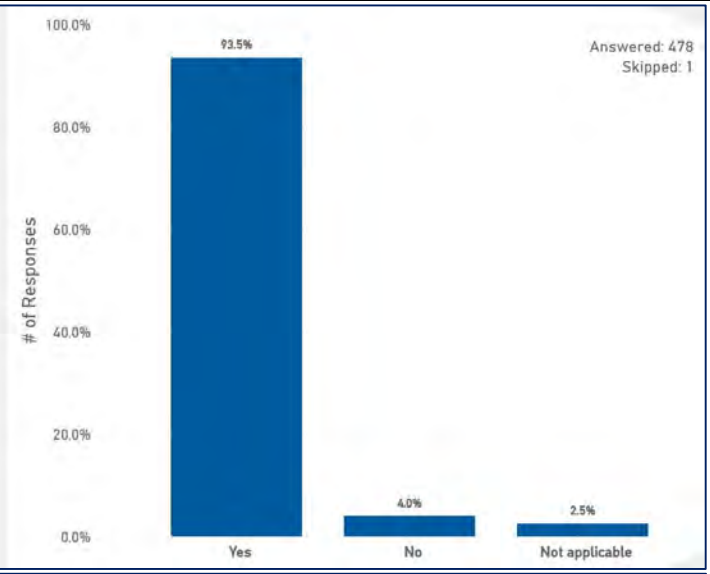
All Responses



26. Does your employer require you to complete non-dispensing related services, such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects?

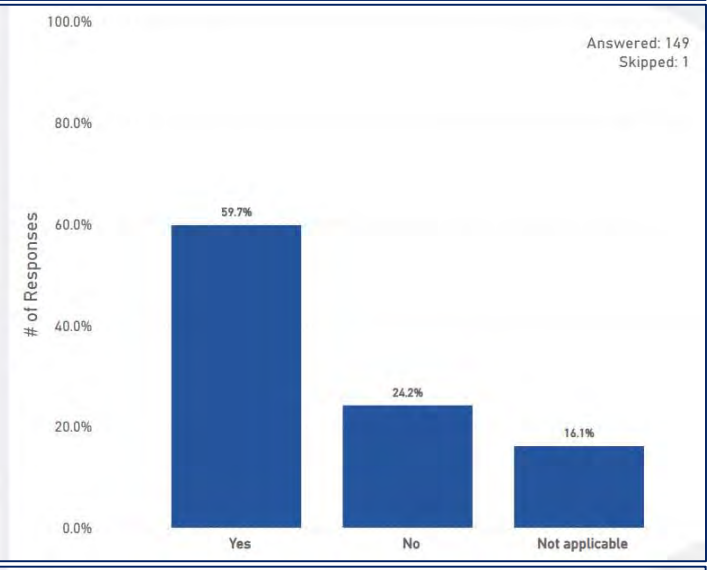
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	447	93.5%
No	19	4.0%
Not applicable	12	2.5%
Total	**478**	**100.0%**



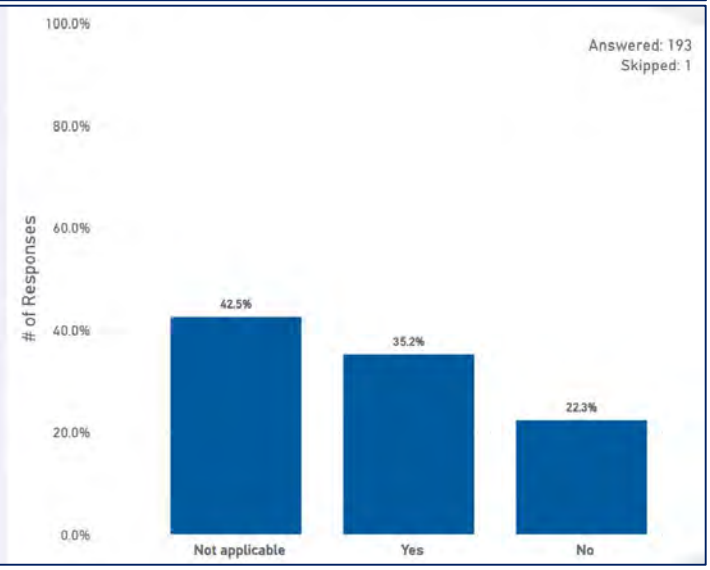
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	89	59.7%
No	36	24.2%
Not applicable	24	16.1%
Total	**149**	**100.0%**



Other

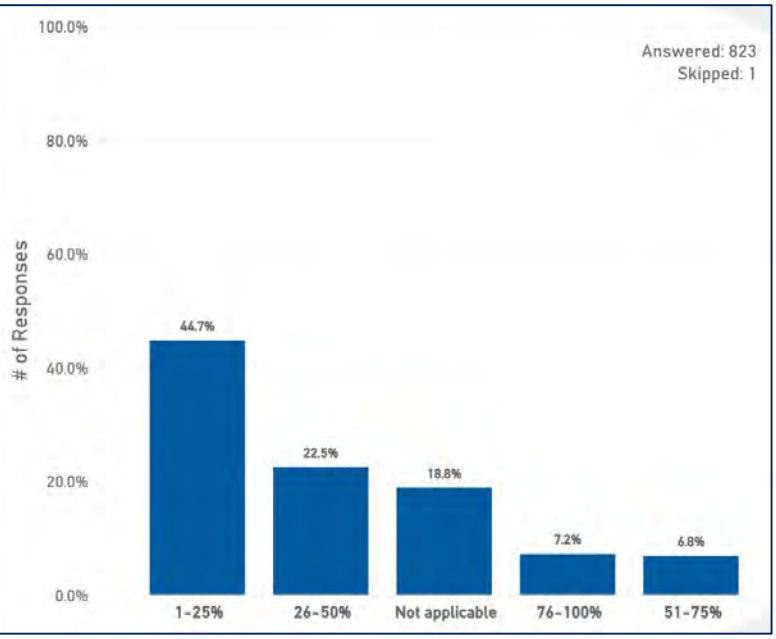
Survey Responses	# Responses	% Responses
Not applicable	82	42.5%
Yes	68	35.2%
No	43	22.3%
Total	**193**	**100.0%**



27. On average, what percentage of your time is spent on non-dispensing services?

Survey Responses	# Responses	% Responses
1-25%	368	44.7%
26-50%	185	22.5%
Not applicable	155	18.8%
76-100%	59	7.2%
51-75%	56	6.8%
Total	**823**	**100.0%**

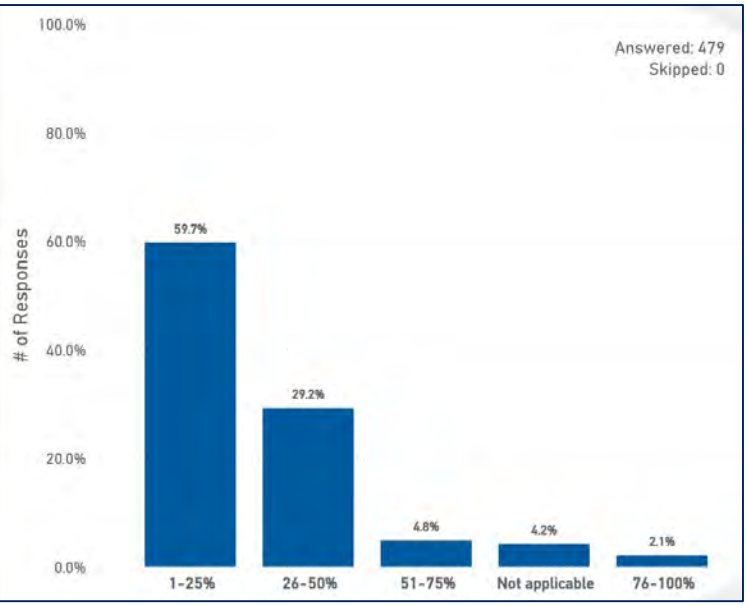
All Responses



27. On average, what percentage of your time is spent on non-dispensing services?

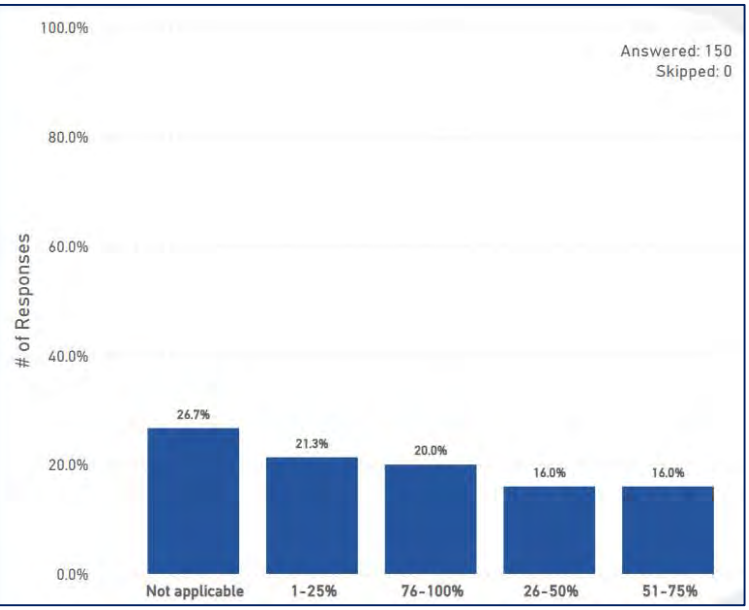
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
1-25%	286	59.7%
26-50%	140	29.2%
51-75%	23	4.8%
Not applicable	20	4.2%
76-100%	10	2.1%
Total	**479**	**100.0%**



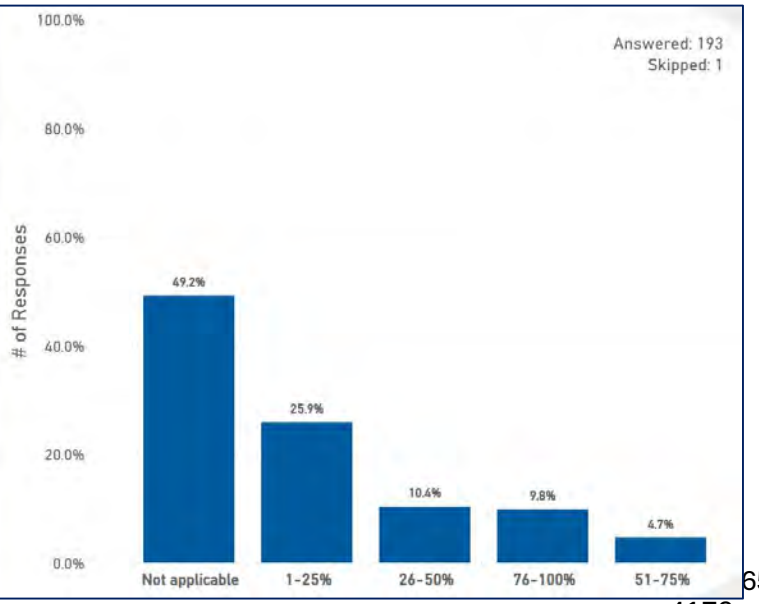
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Not applicable	40	26.7%
1-25%	32	21.3%
76-100%	30	20.0%
26-50%	24	16.0%
51-75%	24	16.0%
Total	**150**	**100.0%**



Other

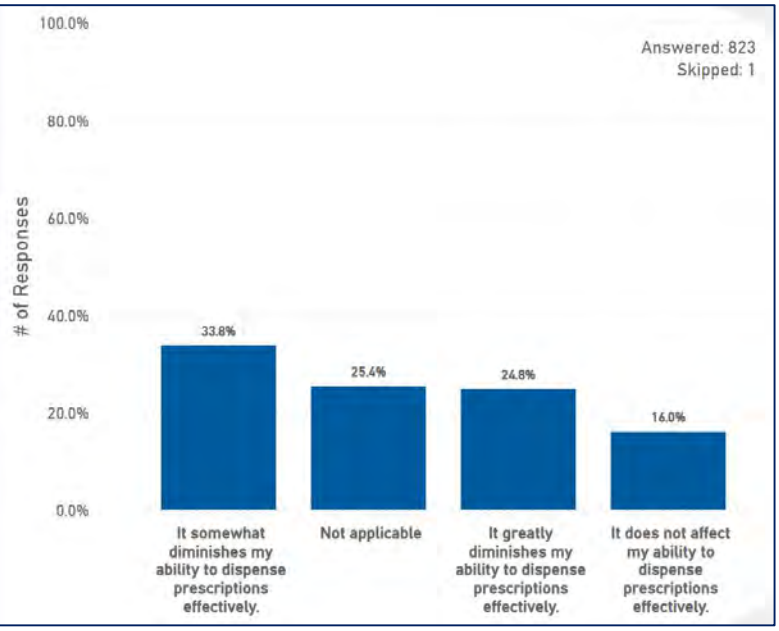
Survey Responses	# Responses	% Responses
Not applicable	95	49.2%
1-25%	50	25.9%
26-50%	20	10.4%
76-100%	19	9.8%
51-75%	9	4.7%
Total	**193**	**100.0%**



28. In your opinion, how does completing non-dispensing services affect your ability to dispense prescriptions effectively?

Survey Responses	# Responses	% Responses
It somewhat diminishes my ability to dispense prescriptions effectively.	278	33.8%
Not applicable	209	25.4%
It greatly diminishes my ability to dispense prescriptions effectively.	204	24.8%
It does not affect my ability to dispense prescriptions effectively.	132	16.0%
Total	**823**	**100.0%**

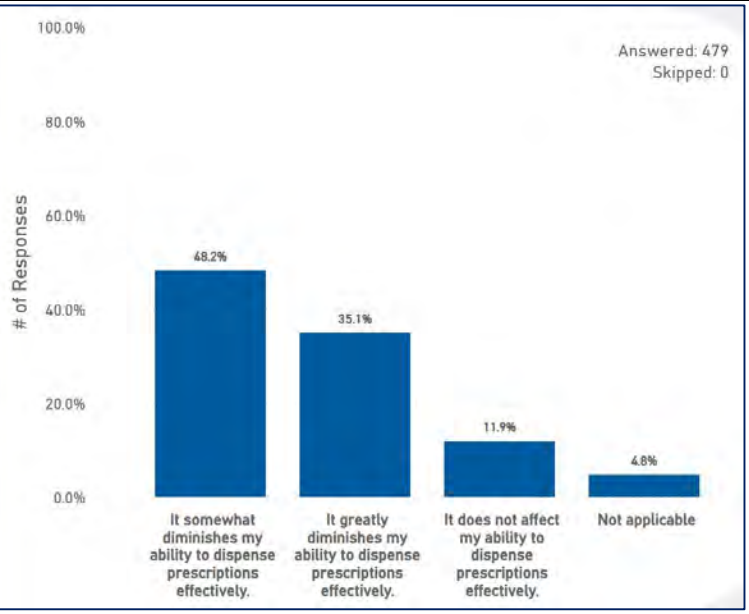
All Responses



28. In your opinion, how does completing non-dispensing services affect your ability to dispense prescriptions effectively?

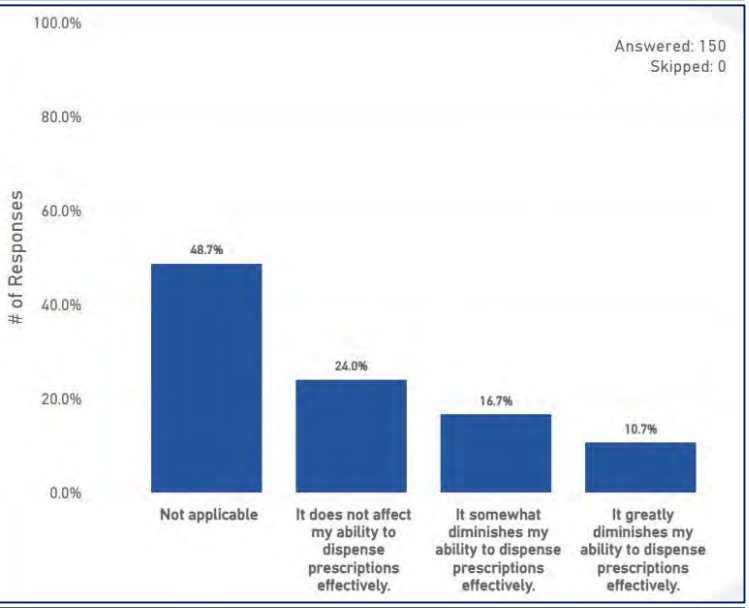
Survey Responses	# Responses	% Responses
It somewhat diminishes my ability to dispense prescriptions effectively.	231	48.2%
It greatly diminishes my ability to dispense prescriptions effectively.	168	35.1%
It does not affect my ability to dispense prescriptions effectively.	57	11.9%
Not applicable	23	4.8%
Total	**479**	**100.0%**

Retail Chain Pharmacist



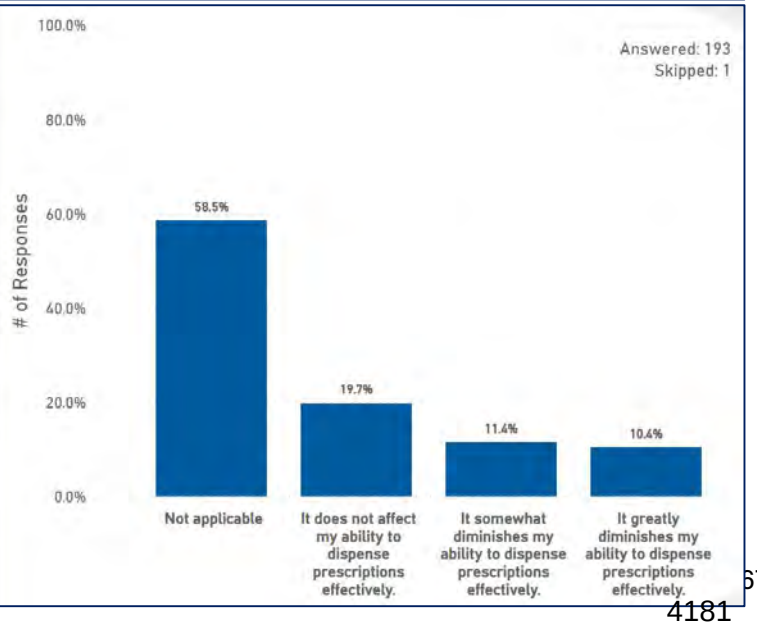
Survey Responses	# Responses	% Responses
Not applicable	73	48.7%
It does not affect my ability to dispense prescriptions effectively.	36	24.0%
It somewhat diminishes my ability to dispense prescriptions effectively.	25	16.7%
It greatly diminishes my ability to dispense prescriptions effectively.	16	10.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	113	58.5%
It does not affect my ability to dispense prescriptions effectively.	38	19.7%
It somewhat diminishes my ability to dispense prescriptions effectively.	22	11.4%
It greatly diminishes my ability to dispense prescriptions effectively.	20	10.4%
Total	**193**	**100.0%**

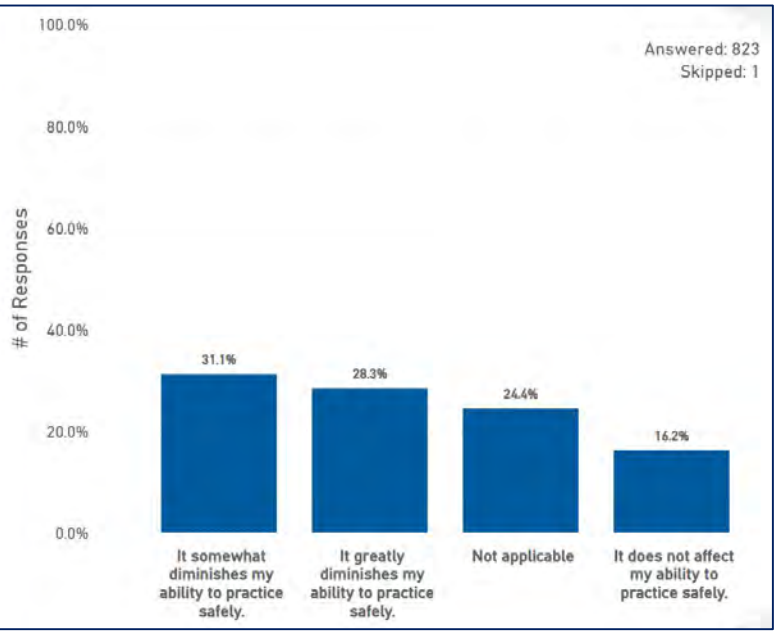
Other



29. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect your ability to practice safely?

Survey Responses	# Responses	% Responses
It somewhat diminishes my ability to practice safely.	256	31.1%
It greatly diminishes my ability to practice safely.	233	28.3%
Not applicable	201	24.4%
It does not affect my ability to practice safely.	133	16.2%
Total	**823**	**100.0%**

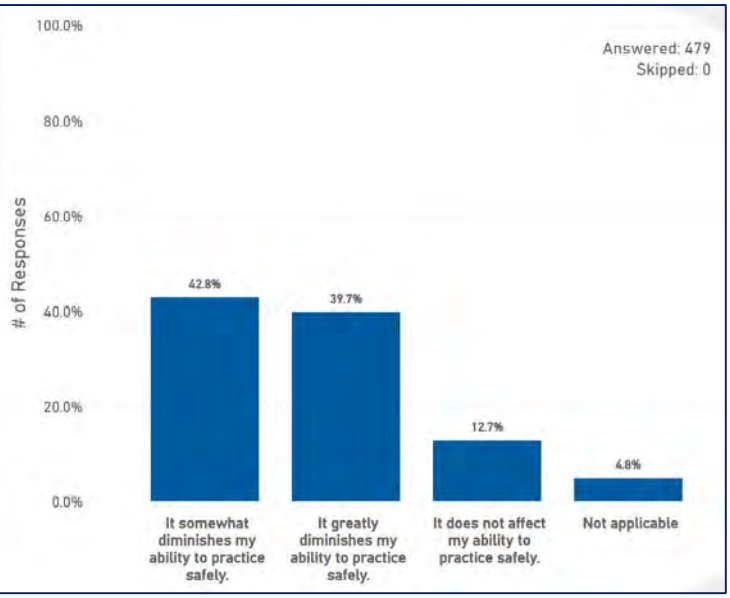
All Responses



29. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect your ability to practice safely?

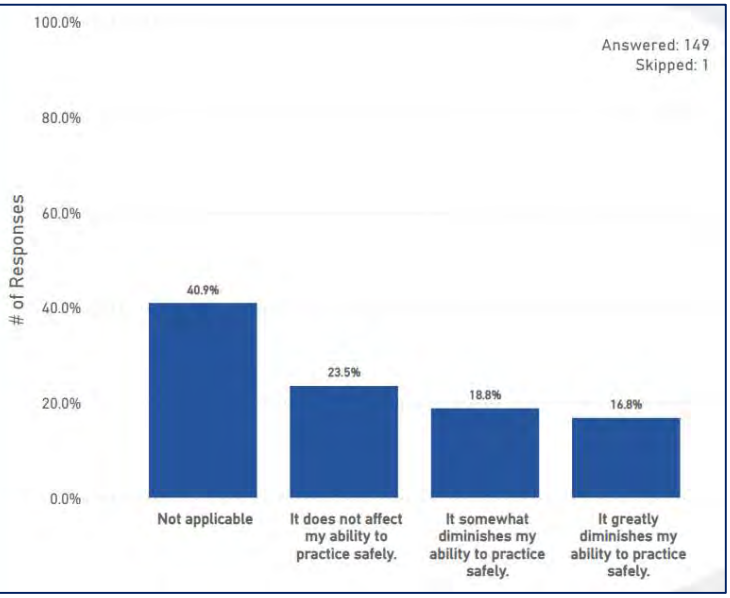
Survey Responses	# Responses	% Responses
It somewhat diminishes my ability to practice safely.	205	42.8%
It greatly diminishes my ability to practice safely.	190	39.7%
It does not affect my ability to practice safely.	61	12.7%
Not applicable	23	4.8%
Total	**479**	**100.0%**

Retail Chain Pharmacist



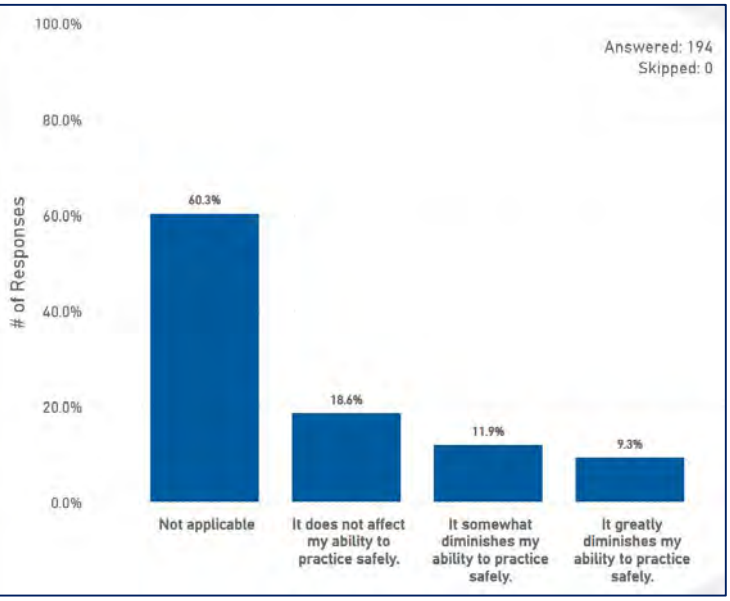
Survey Responses	# Responses	% Responses
Not applicable	61	40.9%
It does not affect my ability to practice safely.	35	23.5%
It somewhat diminishes my ability to practice safely.	28	18.8%
It greatly diminishes my ability to practice safely.	25	16.8%
Total	**149**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	117	60.3%
It does not affect my ability to practice safely.	36	18.6%
It somewhat diminishes my ability to practice safely.	23	11.9%
It greatly diminishes my ability to practice safely.	18	9.3%
Total	**194**	**100.0%**

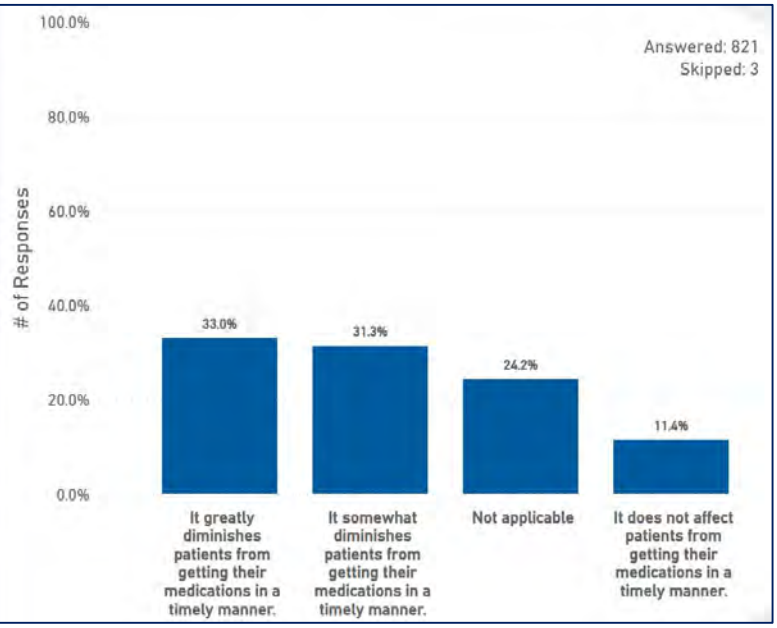
Other



30. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect patients from getting their medications in a timely manner?

Survey Responses	# Responses	% Responses
It greatly diminishes patients from getting their medications in a timely manner.	271	33.0%
It somewhat diminishes patients from getting their medications in a timely manner.	257	31.3%
Not applicable	199	24.2%
It does not affect patients from getting their medications in a timely manner.	94	11.4%
Total	**821**	**100.0%**

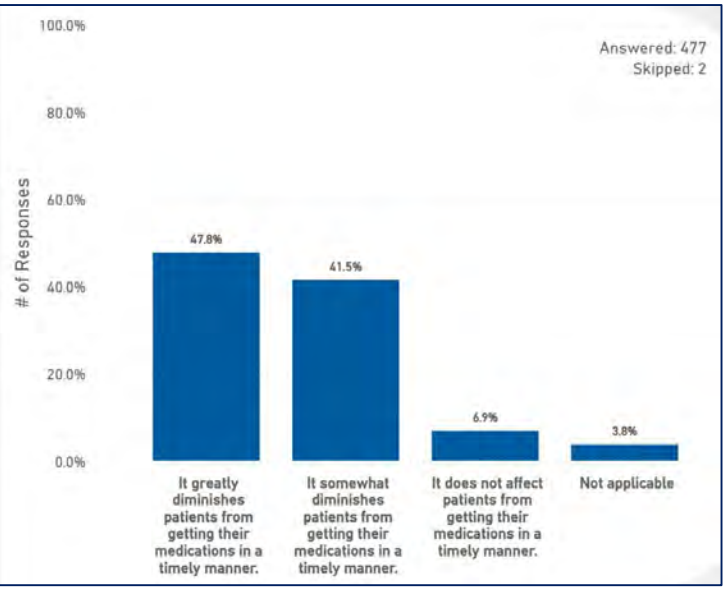
All Responses



30. In your opinion, how does completing non-dispensing services while also engaged in processing prescriptions affect patients from getting their medications in a timely manner?

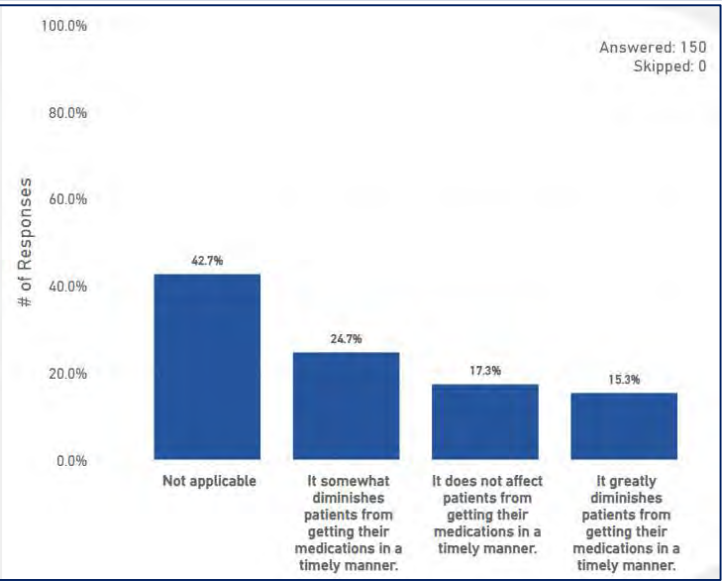
Survey Responses	# Responses	% Responses
It greatly diminishes patients from getting their medications in a timely manner.	228	47.8%
It somewhat diminishes patients from getting their medications in a timely manner.	198	41.5%
It does not affect patients from getting their medications in a timely manner.	33	6.9%
Not applicable	18	3.8%
Total	**477**	**100.0%**

Retail Chain Pharmacist



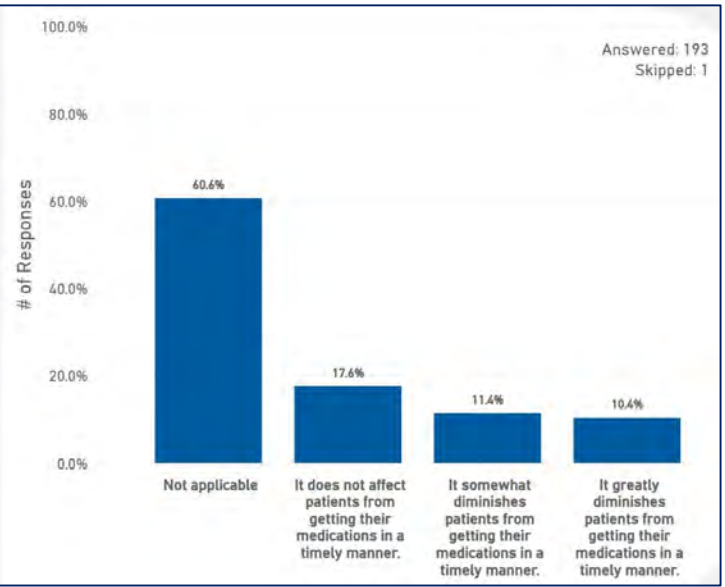
Survey Responses	# Responses	% Responses
Not applicable	64	42.7%
It somewhat diminishes patients from getting their medications in a timely manner.	37	24.7%
It does not affect patients from getting their medications in a timely manner.	26	17.3%
It greatly diminishes patients from getting their medications in a timely manner.	23	15.3%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	117	60.6%
It does not affect patients from getting their medications in a timely manner.	34	17.6%
It somewhat diminishes patients from getting their medications in a timely manner.	22	11.4%
It greatly diminishes patients from getting their medications in a timely manner.	20	10.4%
Total	**193**	**100.0%**

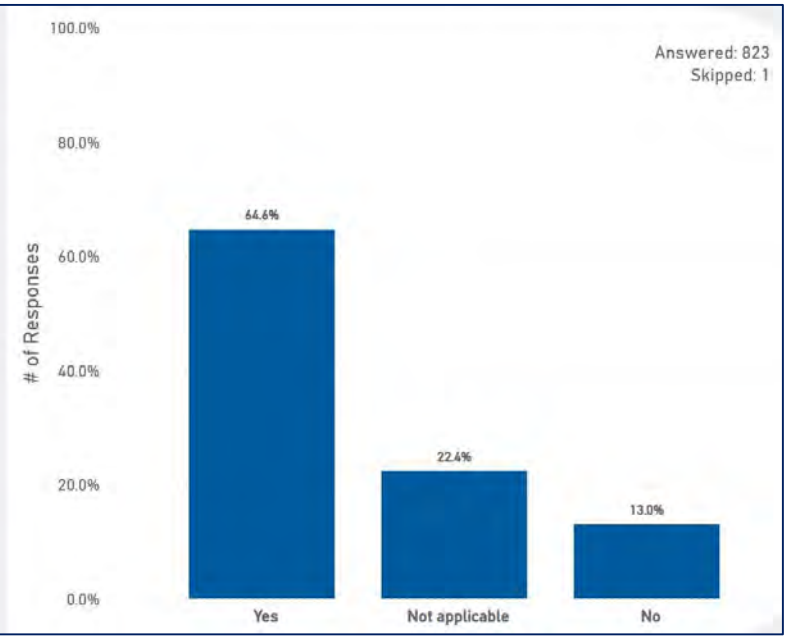
Other



31. Does your employer at your primary practice setting use workload metrics to measure one or more of following areas: number of immunizations, number of refill requests, number of patients enrolled in autofill, number of prescriptions filled, number of MTM services completed, average time to fill a new prescription, average time to fill a refill, average wait time for prescriptions, OR other metrics?

Survey Responses	# Responses	% Responses
Yes	532	64.6%
Not applicable	184	22.4%
No	107	13.0%
Total	**823**	**100.0%**

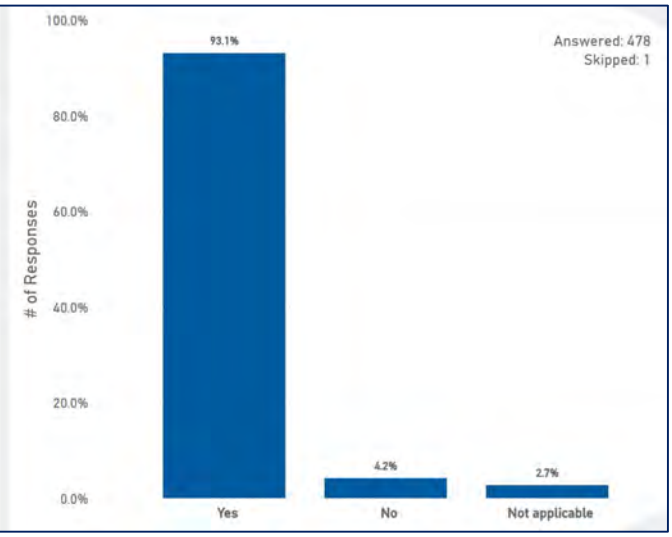
All Responses



31. Does your employer at your primary practice setting use workload metrics to measure one or more of following areas: number of immunizations, number of refill requests, number of patients enrolled in autofill, number of prescriptions filled, number of MTM services completed, average time to fill a new prescription, average time to fill a refill, average wait time for prescriptions, OR other metrics?

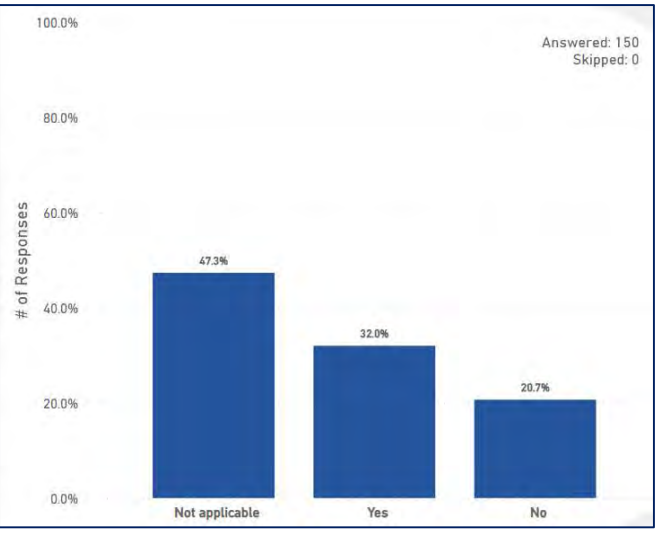
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	445	93.1%
No	20	4.2%
Not applicable	13	2.7%
Total	**478**	**100.0%**



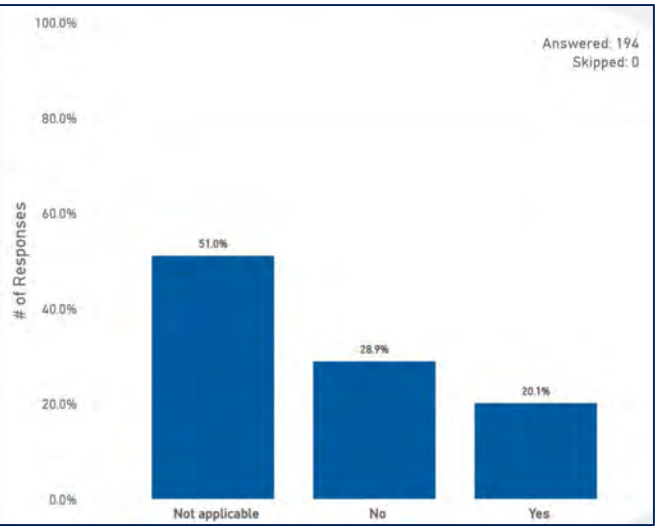
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Not applicable	71	47.3%
Yes	48	32.0%
No	31	20.7%
Total	**150**	**100.0%**



Other

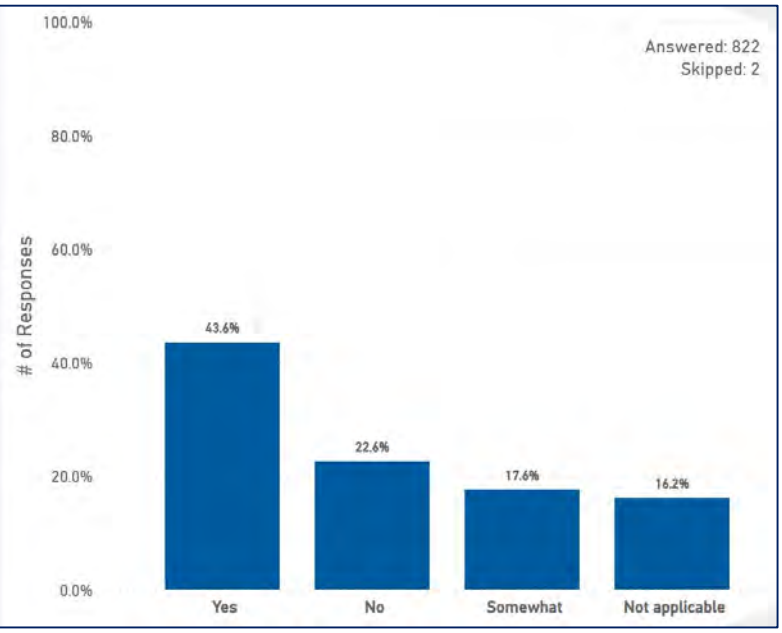
Survey Responses	# Responses	% Responses
Not applicable	99	51.0%
No	56	28.9%
Yes	39	20.1%
Total	**194**	**100.0%**



32. Do you feel that you have been pressured by your employer or supervisor to meet standards or metrics that may interfere with safe patient care?

Survey Responses	# Responses	% Responses
Yes	358	43.6%
No	186	22.6%
Somewhat	145	17.6%
Not applicable	133	16.2%
Total	**822**	**100.0%**

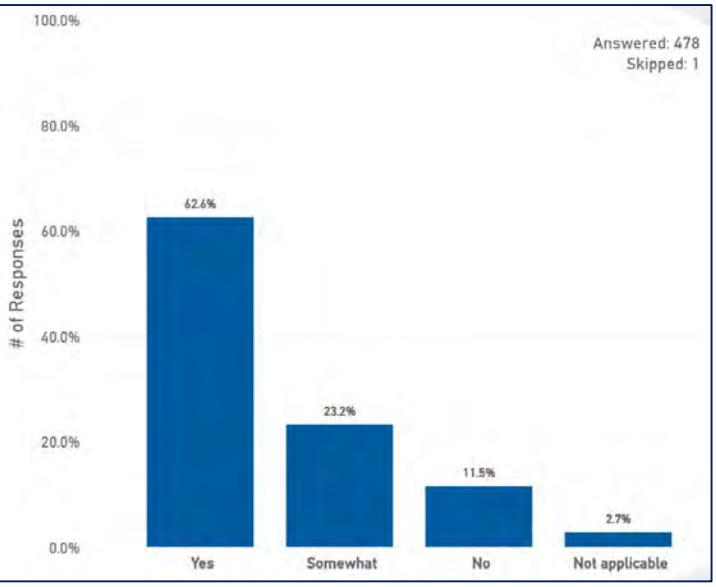
All Responses



32. Do you feel that you have been pressured by your employer or supervisor to meet standards or metrics that may interfere with safe patient care?

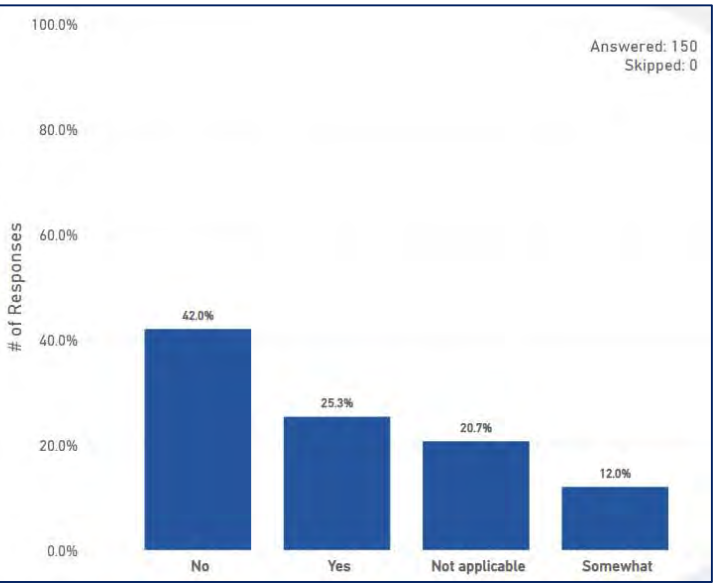
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	299	62.6%
Somewhat	111	23.2%
No	55	11.5%
Not applicable	13	2.7%
Total	**478**	**100.0%**



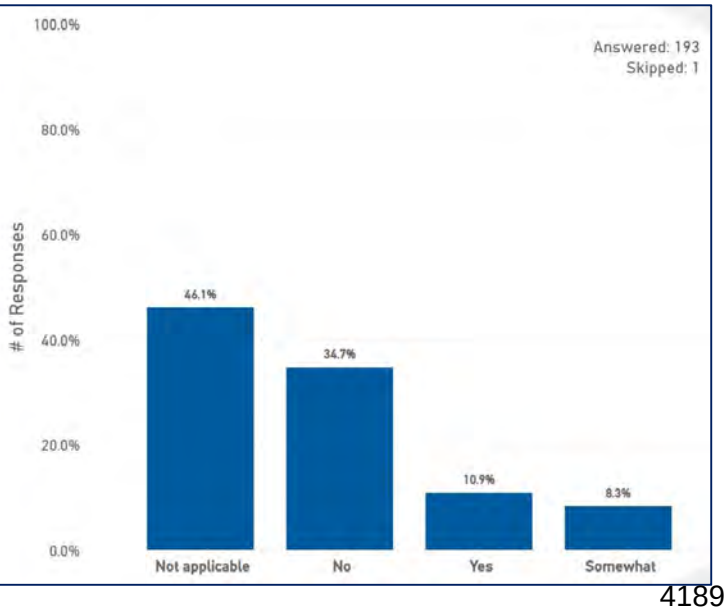
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
No	63	42.0%
Yes	38	25.3%
Not applicable	31	20.7%
Somewhat	18	12.0%
Total	**150**	**100.0%**



Other

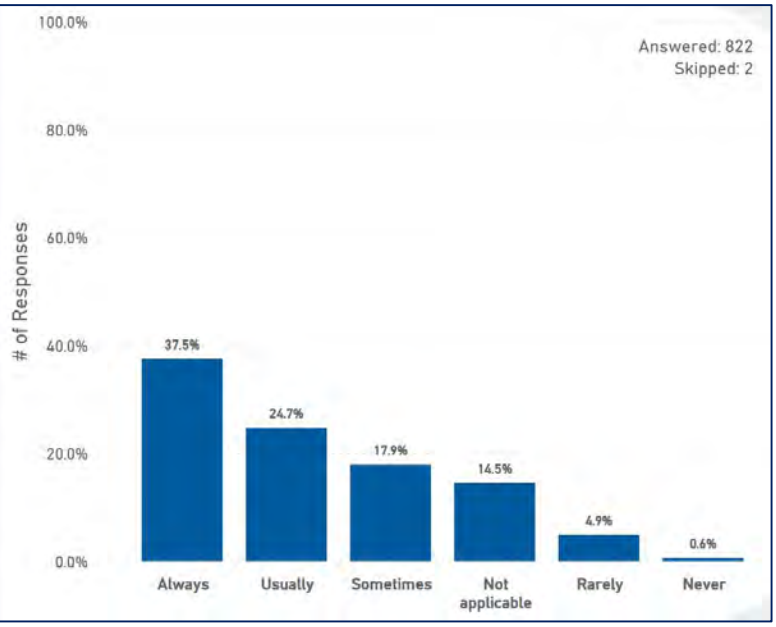
Survey Responses	# Responses	% Responses
Not applicable	89	46.1%
No	67	34.7%
Yes	21	10.9%
Somewhat	16	8.3%
Total	**193**	**100.0%**



33. On average, how frequently are you interrupted while processing a prescription?

Survey Responses	# Responses	% Responses
Always	308	37.5%
Usually	203	24.7%
Sometimes	147	17.9%
Not applicable	119	14.5%
Rarely	40	4.9%
Never	5	0.6%
Total	**822**	**100.0%**

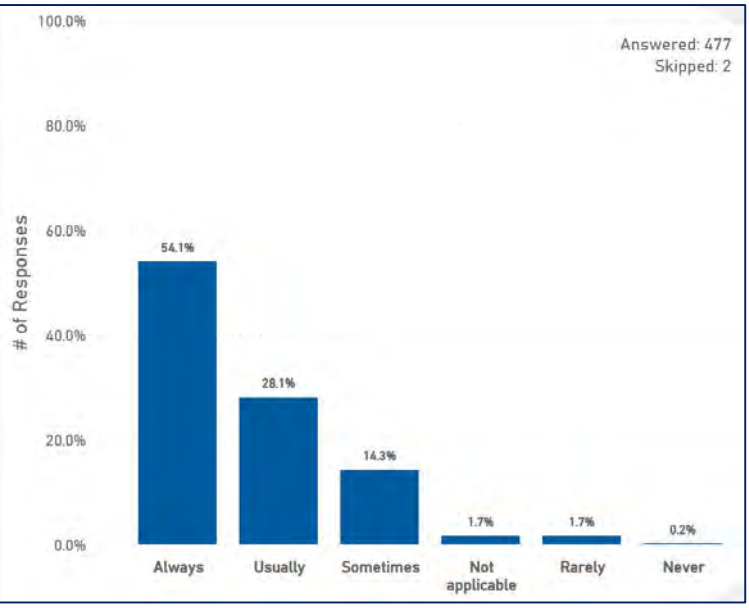
All Responses



33. On average, how frequently are you interrupted while processing a prescription?

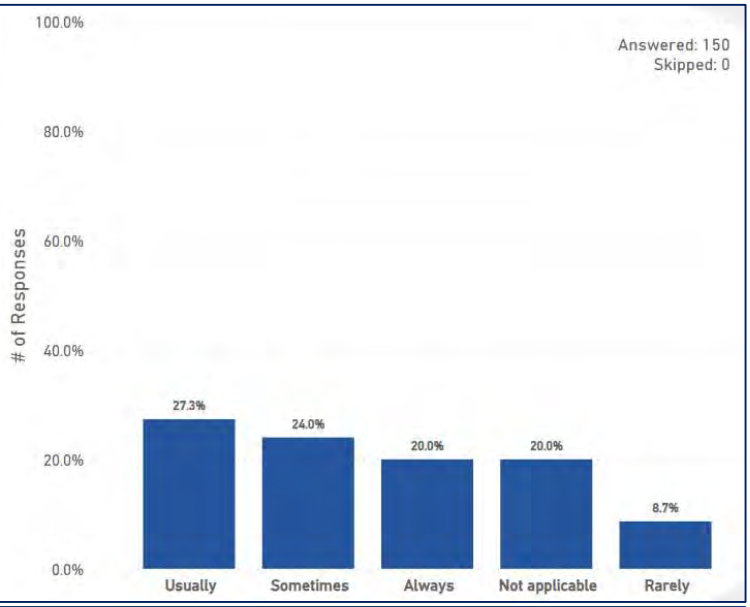
Survey Responses	# Responses	% Responses
Always	258	54.1%
Usually	134	28.1%
Sometimes	68	14.3%
Not applicable	8	1.7%
Rarely	8	1.7%
Never	1	0.2%
Total	**477**	**100.0%**

Retail Chain Pharmacist



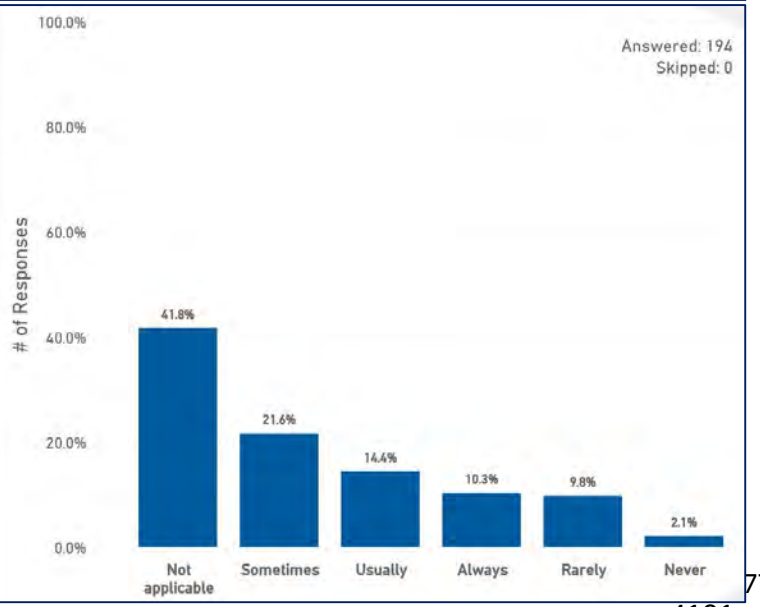
Survey Responses	# Responses	% Responses
Usually	41	27.3%
Sometimes	36	24.0%
Always	30	20.0%
Not applicable	30	20.0%
Rarely	13	8.7%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	81	41.8%
Sometimes	42	21.6%
Usually	28	14.4%
Always	20	10.3%
Rarely	19	9.8%
Never	4	2.1%
Total	**194**	**100.0%**

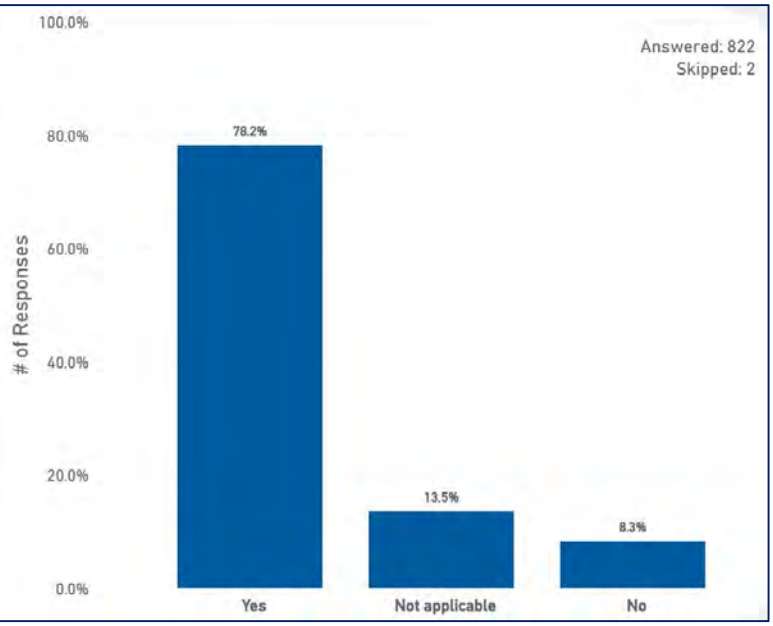
Other



34. Do you fear that interruptions while processing a prescription may lead to a medication error?

Survey Responses	# Responses	% Responses
Yes	643	78.2%
Not applicable	111	13.5%
No	68	8.3%
Total	**822**	**100.0%**

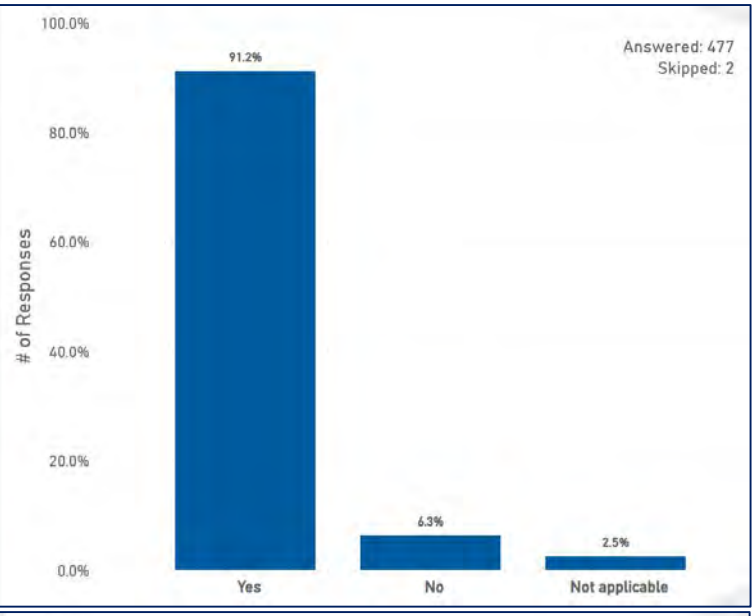
All Responses



34. Do you fear that interruptions while processing a prescription may lead to a medication error?

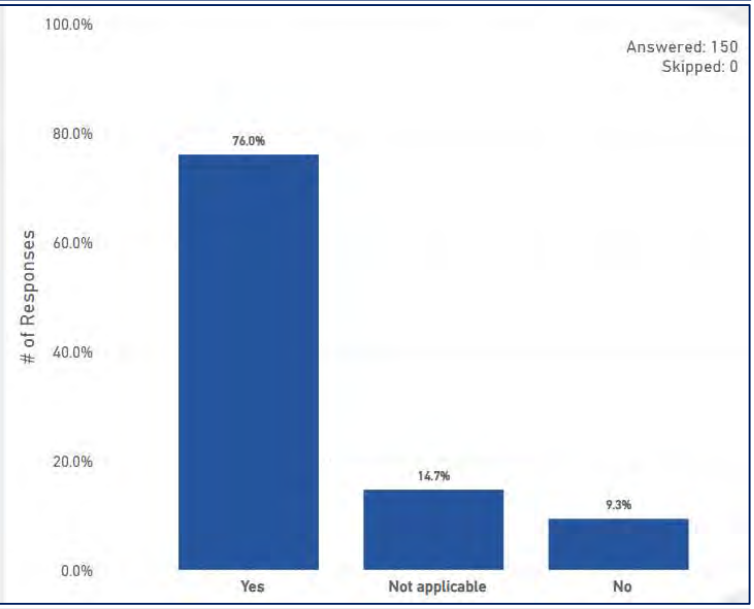
Survey Responses	# Responses	% Responses
Yes	435	91.2%
No	30	6.3%
Not applicable	12	2.5%
Total	**477**	**100.0%**

Retail Chain Pharmacist



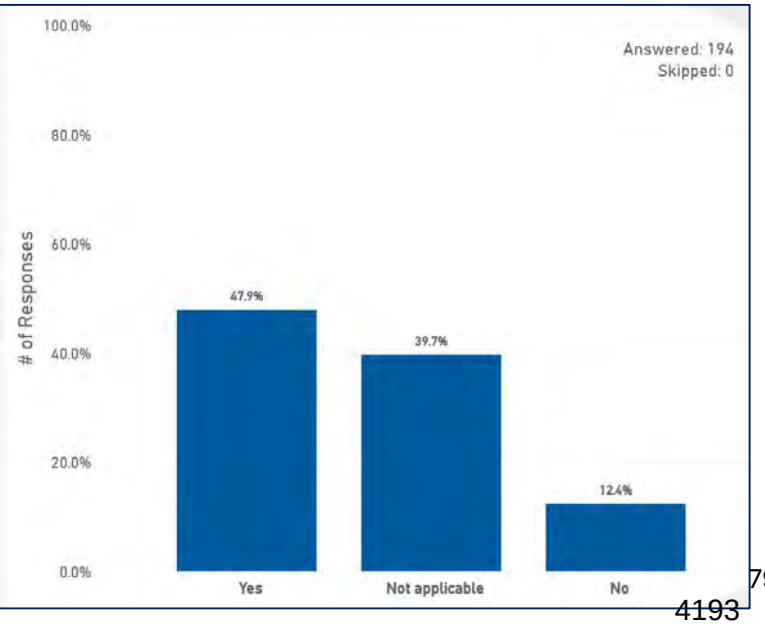
Survey Responses	# Responses	% Responses
Yes	114	76.0%
Not applicable	22	14.7%
No	14	9.3%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Yes	93	47.9%
Not applicable	77	39.7%
No	24	12.4%
Total	**194**	**100.0%**

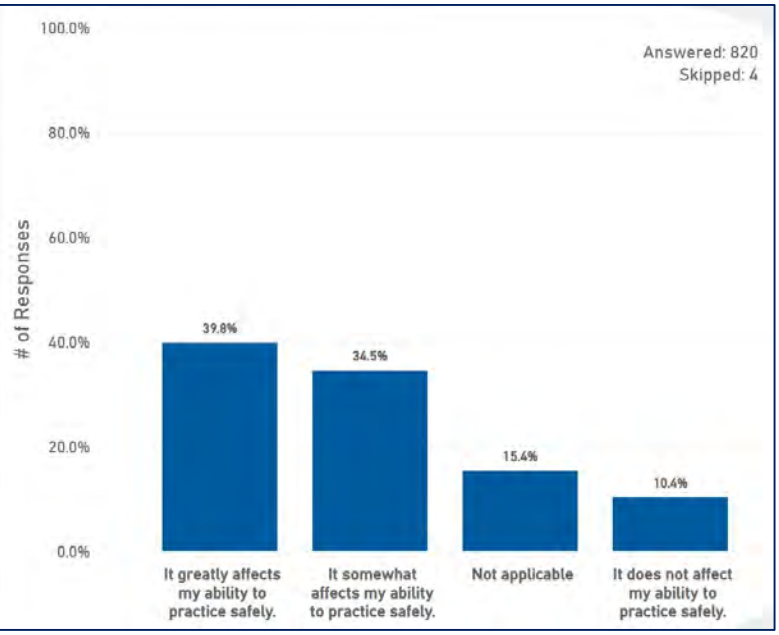
Other



35. In your opinion, how do interruptions while processing a prescription affect your ability to practice safely?

Survey Responses	# Responses	% Responses
It greatly affects my ability to practice safely.	326	39.8%
It somewhat affects my ability to practice safely.	283	34.5%
Not applicable	126	15.4%
It does not affect my ability to practice safely.	85	10.4%
Total	**820**	**100.0%**

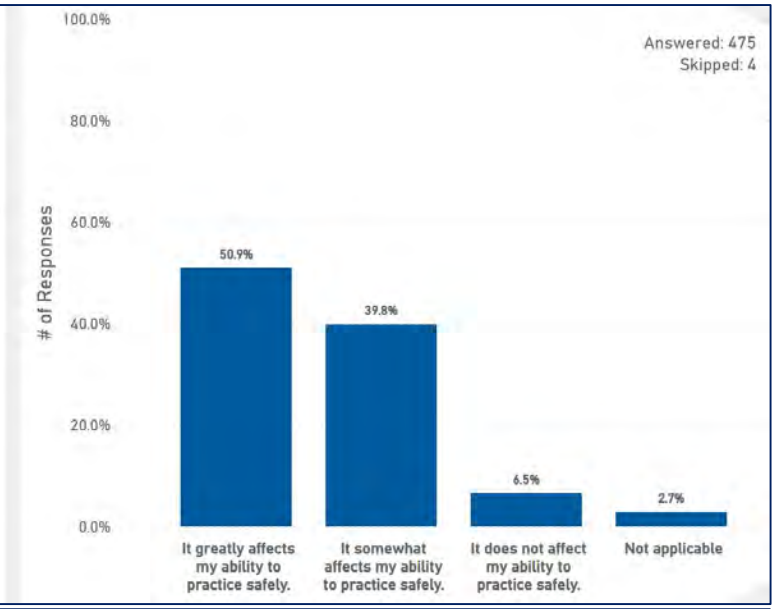
All Responses



35. In your opinion, how do interruptions while processing a prescription affect your ability to practice safely?

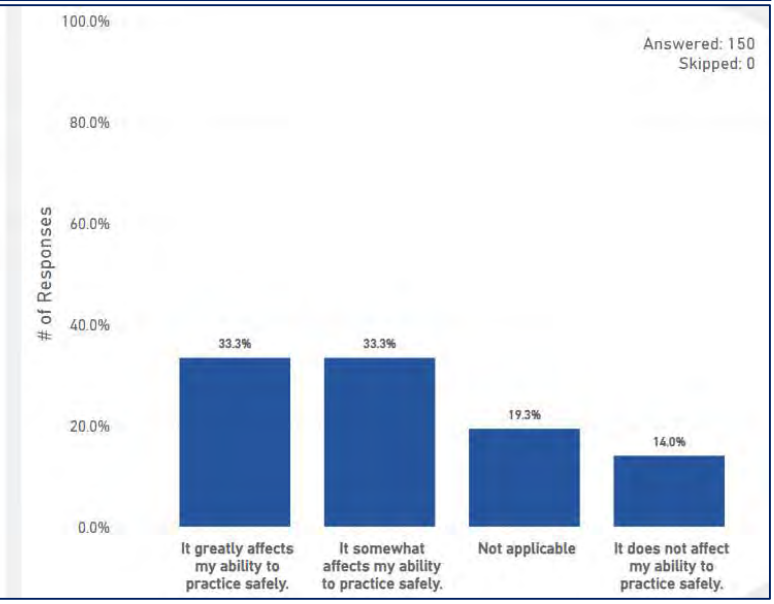
Survey Responses	# Responses	% Responses
It greatly affects my ability to practice safely.	242	50.9%
It somewhat affects my ability to practice safely.	189	39.8%
It does not affect my ability to practice safely.	31	6.5%
Not applicable	13	2.7%
Total	**475**	**100.0%**

Retail Chain Pharmacist



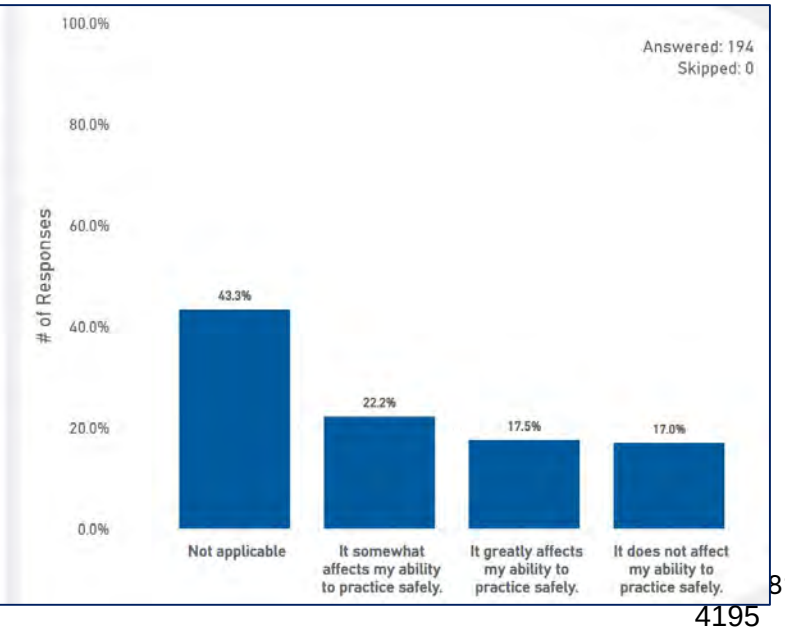
Survey Responses	# Responses	% Responses
It greatly affects my ability to practice safely.	50	33.3%
It somewhat affects my ability to practice safely.	50	33.3%
Not applicable	29	19.3%
It does not affect my ability to practice safely.	21	14.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	84	43.3%
It somewhat affects my ability to practice safely.	43	22.2%
It greatly affects my ability to practice safely.	34	17.5%
It does not affect my ability to practice safely.	33	17.0%
Total	**194**	**100.0%**

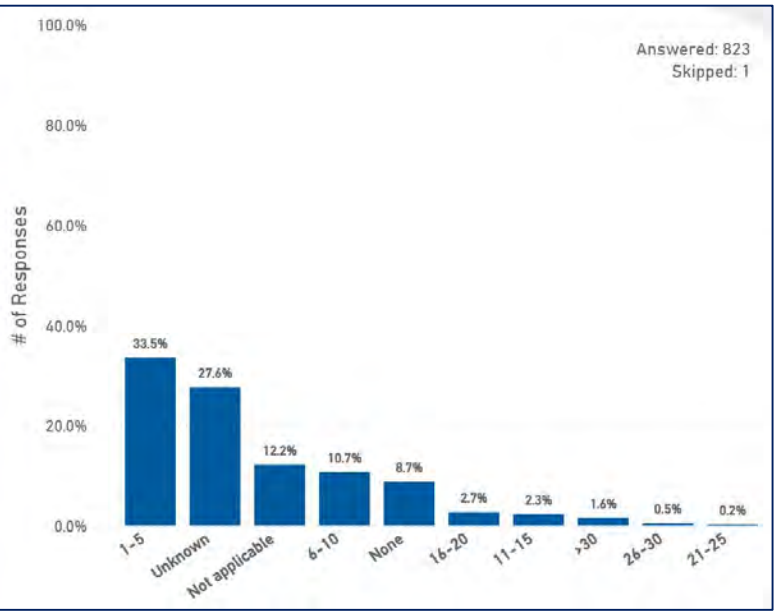
Other



36. What is the average number of medication errors that leave the pharmacy, if any, do you believe occur monthly at your primary practice setting?

Survey Responses	# Responses	% Responses
1-5	276	33.5%
Unknown	227	27.6%
Not applicable	100	12.2%
6-10	88	10.7%
None	72	8.7%
16-20	22	2.7%
11-15	19	2.3%
>30	13	1.6%
26-30	4	0.5%
21-25	2	0.2%
Total	**823**	**100.0%**

All Responses

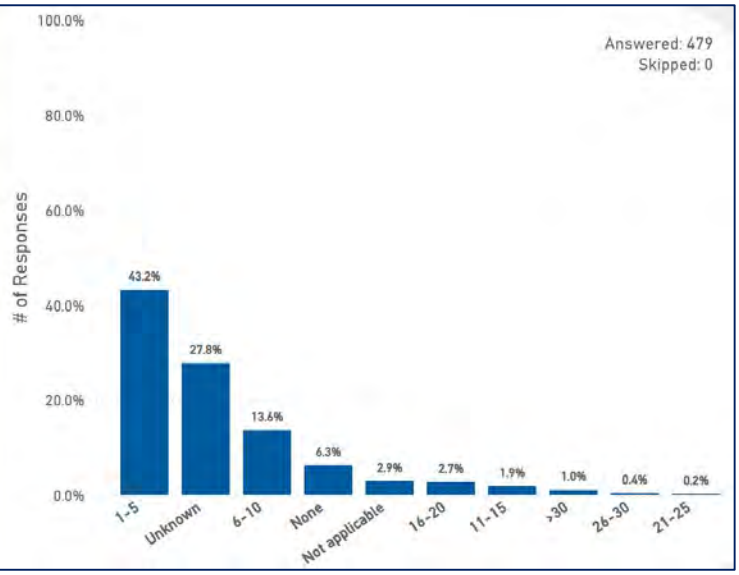


According to the National Coordinating Council for Medication Error Reporting and Prevention, a "medication error" is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

36. What is the average number of medication errors that leave the pharmacy, if any, do you believe occur monthly at your primary practice setting?

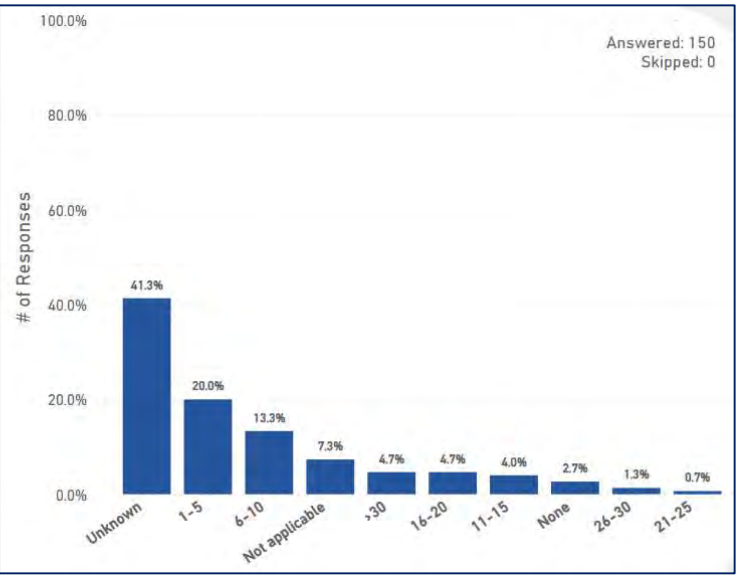
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
1-5	207	43.2%
Unknown	133	27.8%
6-10	65	13.6%
None	30	6.3%
Not applicable	14	2.9%
16-20	13	2.7%
11-15	9	1.9%
>30	5	1.0%
26-30	2	0.4%
21-25	1	0.2%
Total	**479**	**100.0%**



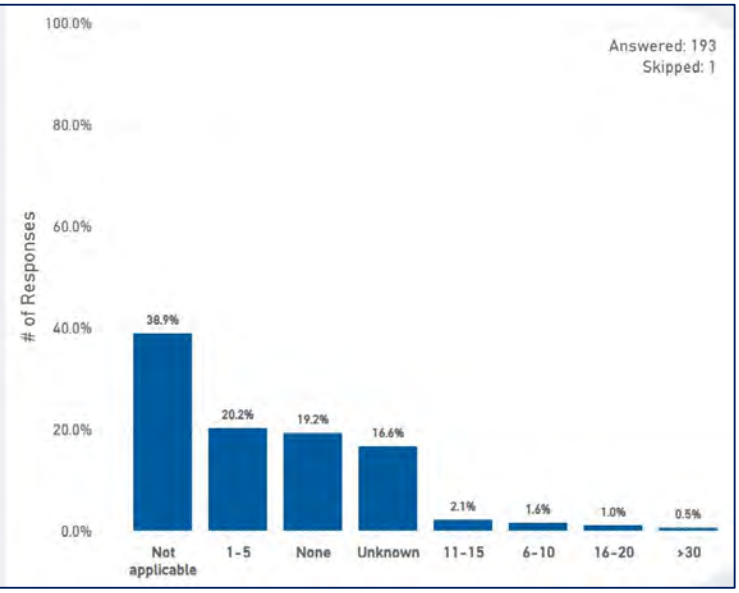
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Unknown	62	41.3%
1-5	30	20.0%
6-10	20	13.3%
Not applicable	11	7.3%
>30	7	4.7%
16-20	7	4.7%
11-15	6	4.0%
None	4	2.7%
26-30	2	1.3%
21-25	1	0.7%
Total	**150**	**100.0%**



Other

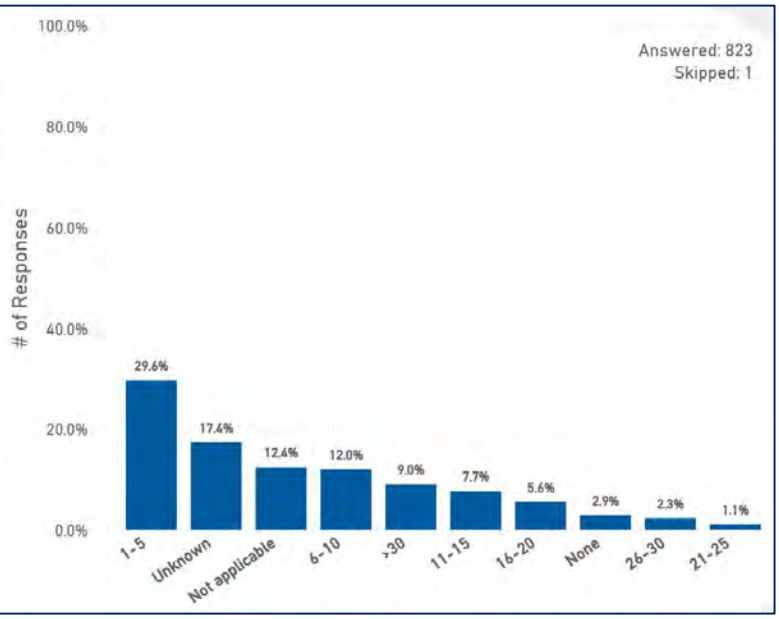
Survey Responses	# Responses	% Responses
Not applicable	75	38.9%
1-5	39	20.2%
None	37	19.2%
Unknown	32	16.6%
11-15	4	2.1%
6-10	3	1.6%
16-20	2	1.0%
>30	1	0.5%
Total	**193**	**100.0%**



37. What is the average number of medication errors that were caught before it left the pharmacy, if any, do you believe occur monthly at your primary practice setting?

Survey Responses	# Responses	% Responses
1-5	244	29.6%
Unknown	143	17.4%
Not applicable	102	12.4%
6-10	99	12.0%
>30	74	9.0%
11-15	63	7.7%
16-20	46	5.6%
None	24	2.9%
26-30	19	2.3%
21-25	9	1.1%
Total	**823**	**100.0%**

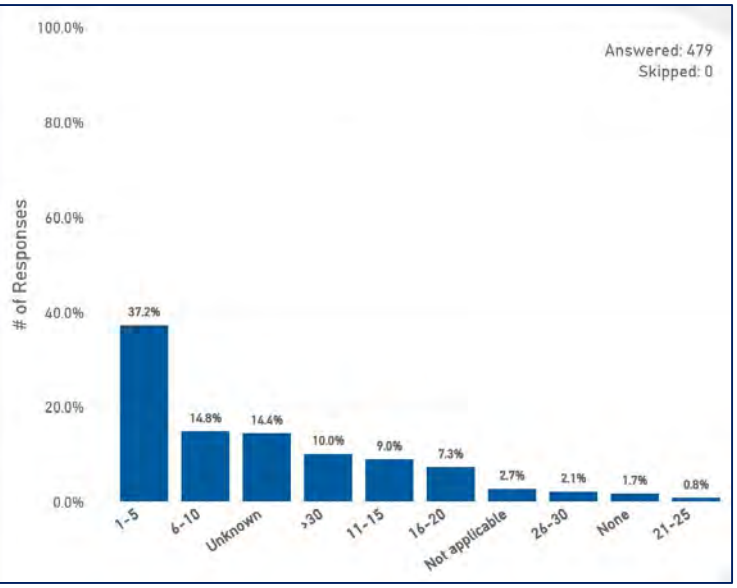
All Responses



37. What is the average number of medication errors that were caught before it left the pharmacy, if any, do you believe occur monthly at your primary practice setting?

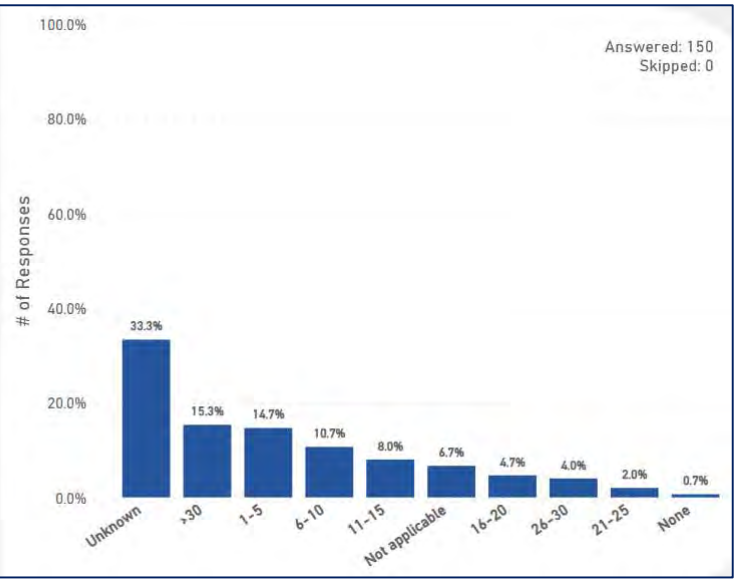
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
1-5	178	37.2%
6-10	71	14.8%
Unknown	69	14.4%
>30	48	10.0%
11-15	43	9.0%
16-20	35	7.3%
Not applicable	13	2.7%
26-30	10	2.1%
None	8	1.7%
21-25	4	0.8%
Total	**479**	**100.0%**



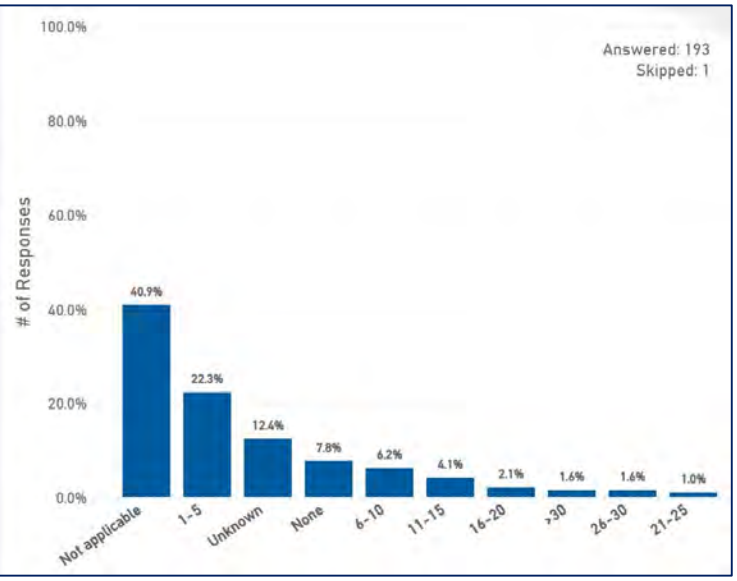
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Unknown	50	33.3%
>30	23	15.3%
1-5	22	14.7%
6-10	16	10.7%
11-15	12	8.0%
Not applicable	10	6.7%
16-20	7	4.7%
26-30	6	4.0%
21-25	3	2.0%
None	1	0.7%
Total	**150**	**100.0%**



Other

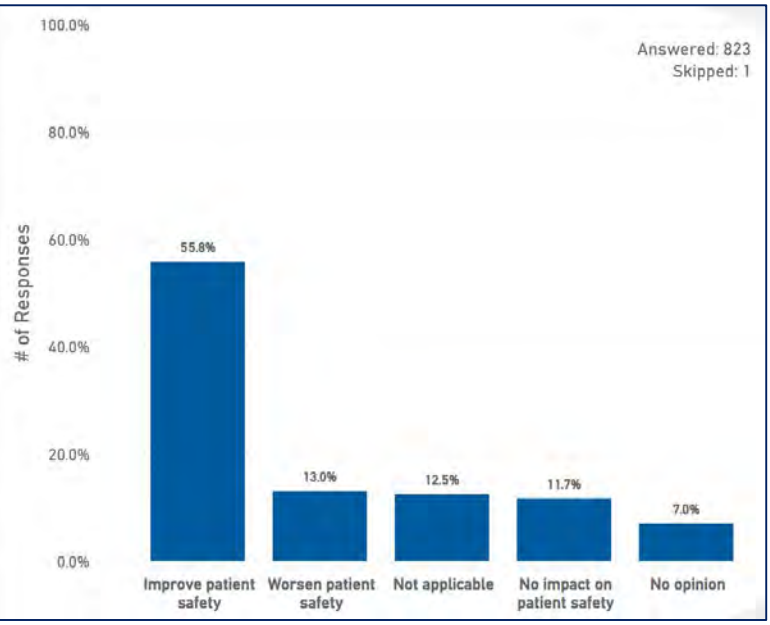
Survey Responses	# Responses	% Responses
Not applicable	79	40.9%
1-5	43	22.3%
Unknown	24	12.4%
None	15	7.8%
6-10	12	6.2%
11-15	8	4.1%
16-20	4	2.1%
>30	3	1.6%
26-30	3	1.6%
21-25	2	1.0%
Total	**193**	**100.0%**



38. In your opinion, how would an increase in the number of Pharmaceutical Technicians (PT) and Pharmaceutical Technicians in Training (PTT) you may supervise in your primary practice setting affect patient safety?

Survey Responses	# Responses	% Responses
Improve patient safety	459	55.8%
Worsen patient safety	107	13.0%
Not applicable	103	12.5%
No impact on patient safety	96	11.7%
No opinion	58	7.0%
Total	**823**	**100.0%**

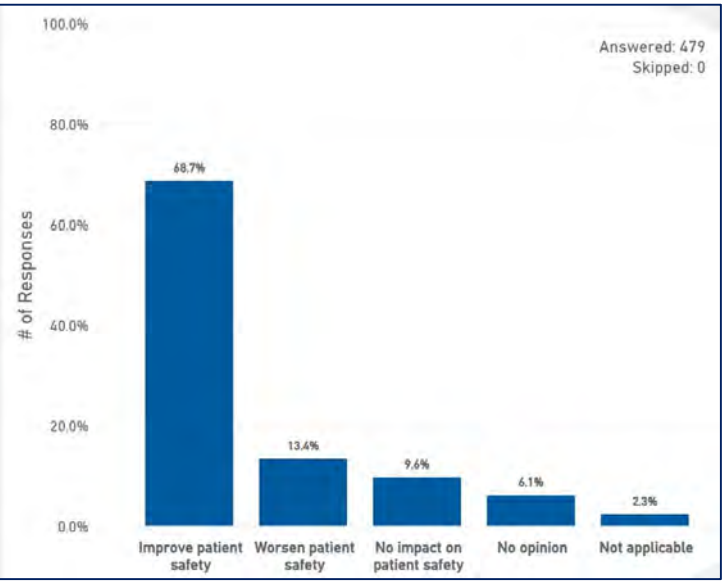
All Responses



38. In your opinion, how would an increase in the number of Pharmaceutical Technicians (PT) and Pharmaceutical Technicians in Training (PTT) you may supervise in your primary practice setting affect patient safety?

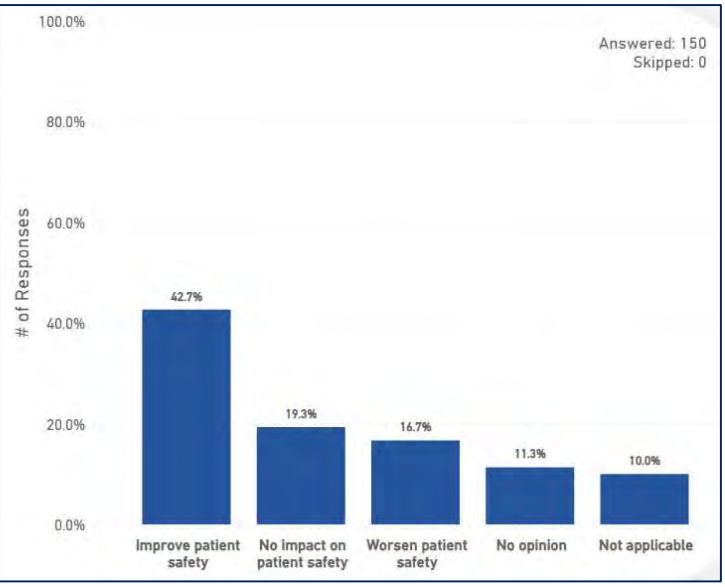
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Improve patient safety	329	68.7%
Worsen patient safety	64	13.4%
No impact on patient safety	46	9.6%
No opinion	29	6.1%
Not applicable	11	2.3%
Total	**479**	**100.0%**



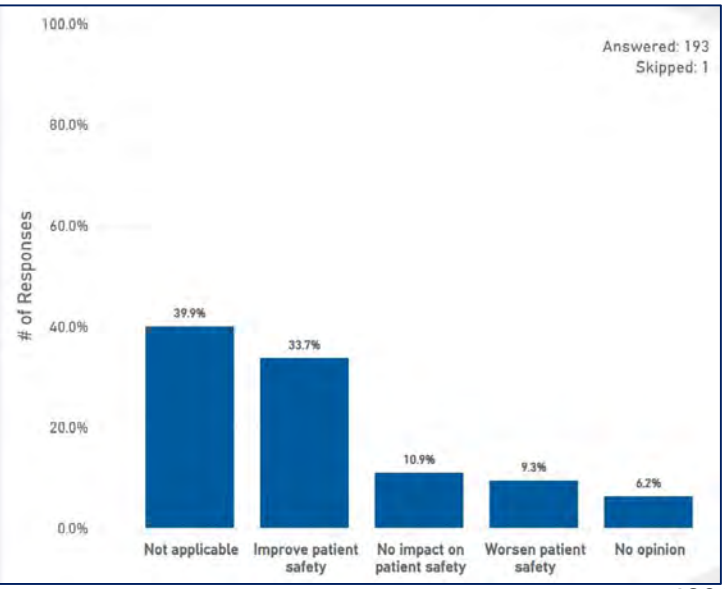
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Improve patient safety	64	42.7%
No impact on patient safety	29	19.3%
Worsen patient safety	25	16.7%
No opinion	17	11.3%
Not applicable	15	10.0%
Total	**150**	**100.0%**



Other

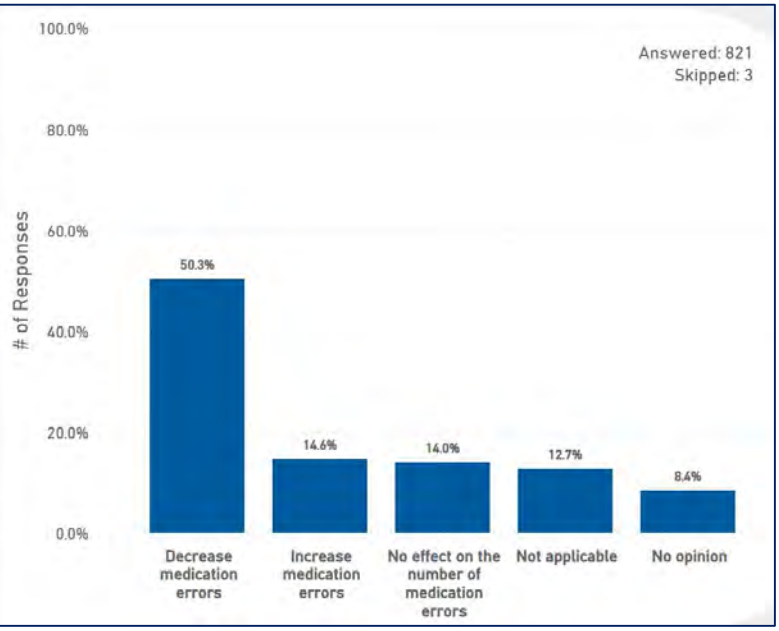
Survey Responses	# Responses	% Responses
Not applicable	77	39.9%
Improve patient safety	65	33.7%
No impact on patient safety	21	10.9%
Worsen patient safety	18	9.3%
No opinion	12	6.2%
Total	**193**	**100.0%**



39. In your opinion, how would an increase in the number of PTs and PTTs you may supervise in your primary practice setting affect medication errors?

Survey Responses	# Responses	% Responses
Decrease medication errors	413	50.3%
Increase medication errors	120	14.6%
No effect on the number of medication errors	115	14.0%
Not applicable	104	12.7%
No opinion	69	8.4%
Total	**821**	**100.0%**

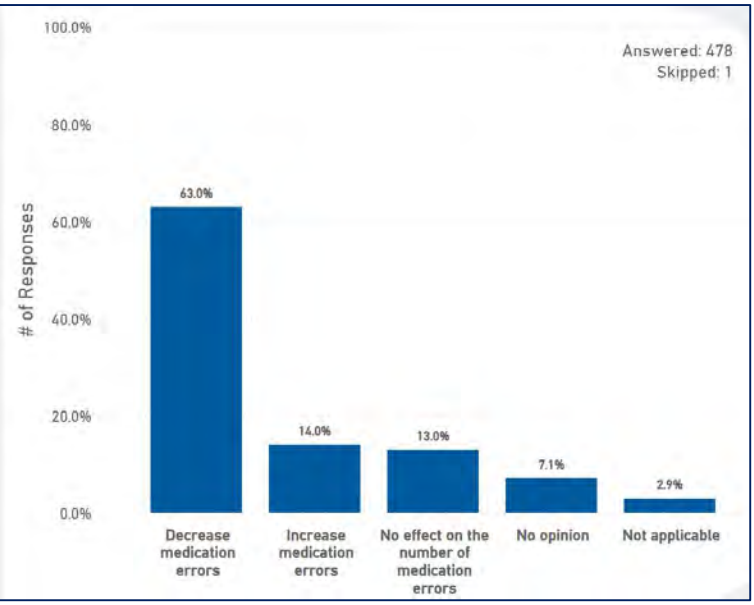
All Responses



39. In your opinion, how would an increase in the number of PTs and PTTs you may supervise in your primary practice setting affect medication errors?

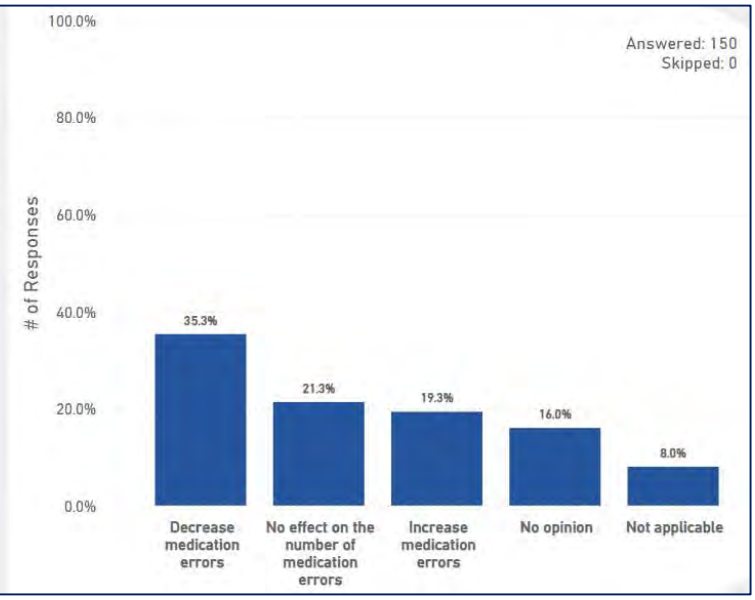
Survey Responses	# Responses	% Responses
Decrease medication errors	301	63.0%
Increase medication errors	67	14.0%
No effect on the number of medication errors	62	13.0%
No opinion	34	7.1%
Not applicable	14	2.9%
Total	**478**	**100.0%**

Retail Chain Pharmacist



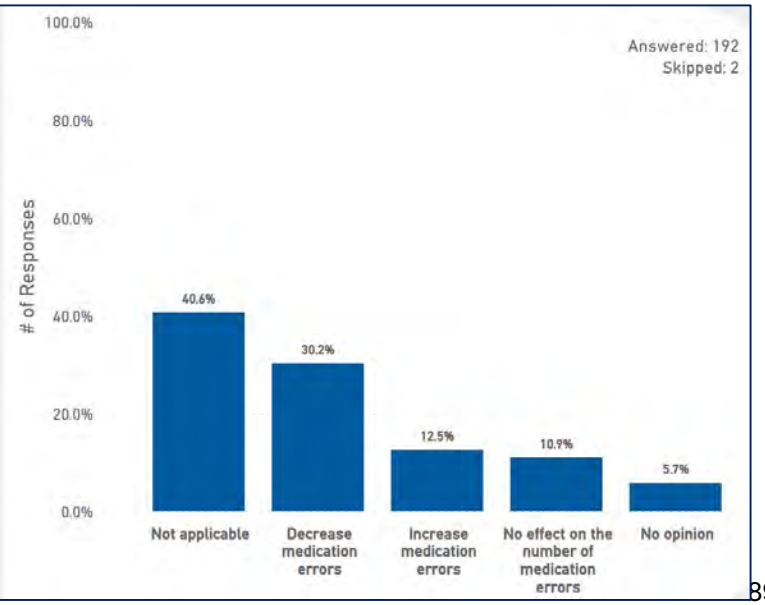
Survey Responses	# Responses	% Responses
Decrease medication errors	53	35.3%
No effect on the number of medication errors	32	21.3%
Increase medication errors	29	19.3%
No opinion	24	16.0%
Not applicable	12	8.0%
Total	**150**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	78	40.6%
Decrease medication errors	58	30.2%
Increase medication errors	24	12.5%
No effect on the number of medication errors	21	10.9%
No opinion	11	5.7%
Total	**192**	**100.0%**

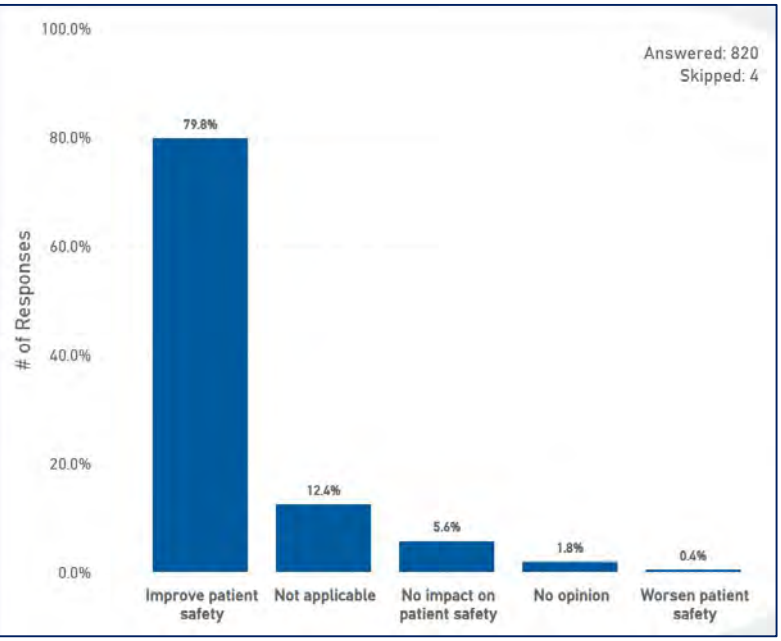
Other



40. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect patient safety?

Survey Responses	# Responses	% Responses
Improve patient safety	654	79.8%
Not applicable	102	12.4%
No impact on patient safety	46	5.6%
No opinion	15	1.8%
Worsen patient safety	3	0.4%
Total	**820**	**100.0%**

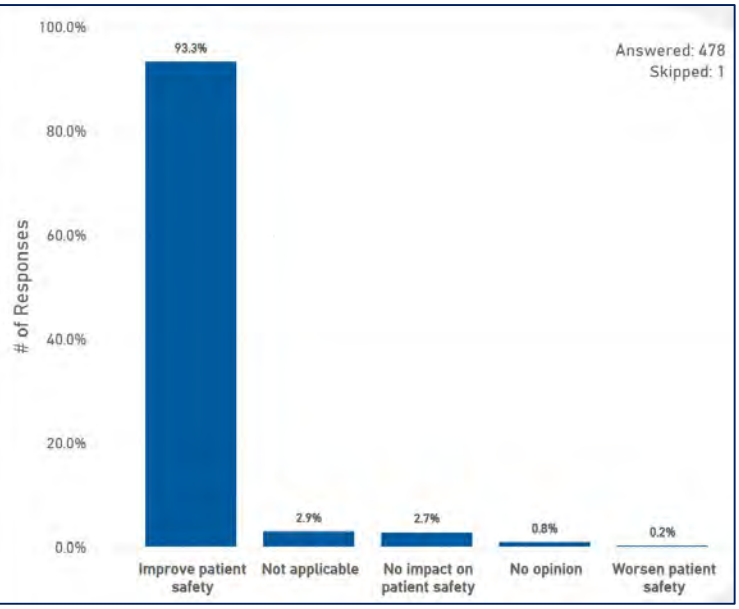
All Responses



40. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect patient safety?

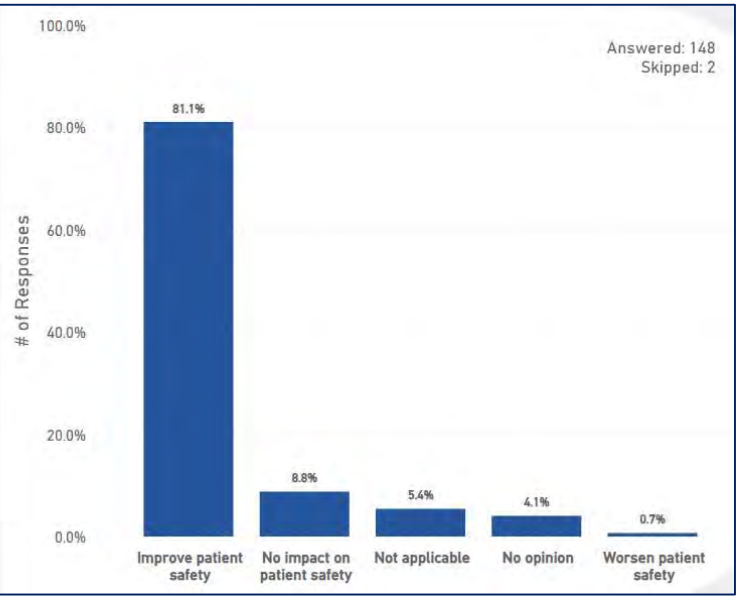
Survey Responses	# Responses	% Responses
Improve patient safety	446	93.3%
Not applicable	14	2.9%
No impact on patient safety	13	2.7%
No opinion	4	0.8%
Worsen patient safety	1	0.2%
Total	**478**	**100.0%**

Retail Chain Pharmacist



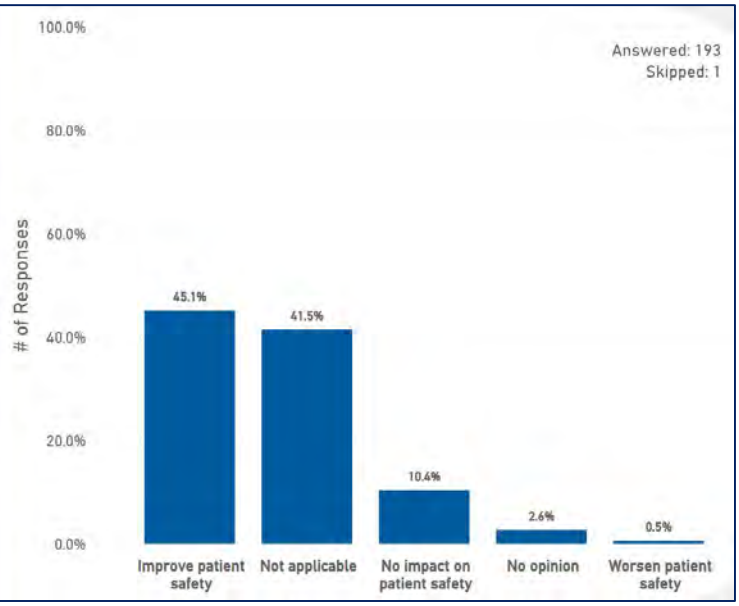
Survey Responses	# Responses	% Responses
Improve patient safety	120	81.1%
No impact on patient safety	13	8.8%
Not applicable	8	5.4%
No opinion	6	4.1%
Worsen patient safety	1	0.7%
Total	**148**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Improve patient safety	87	45.1%
Not applicable	80	41.5%
No impact on patient safety	20	10.4%
No opinion	5	2.6%
Worsen patient safety	1	0.5%
Total	**193**	**100.0%**

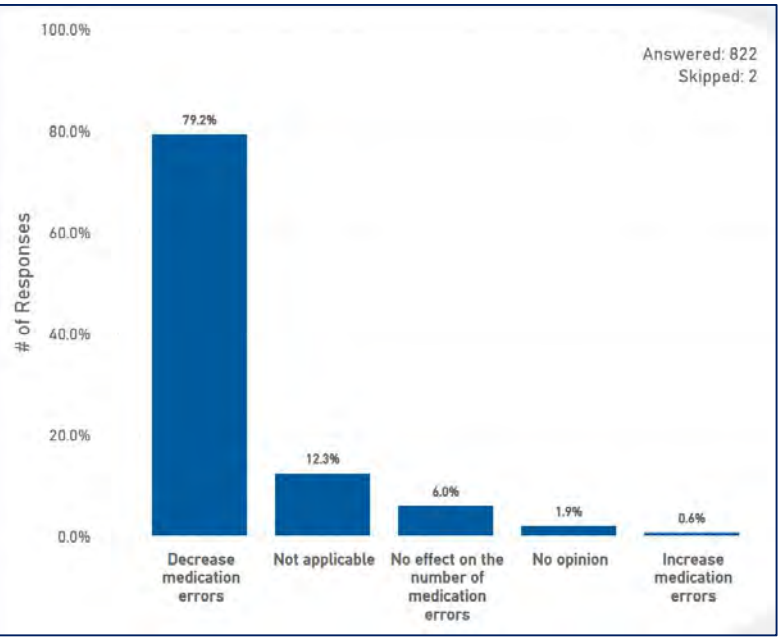
Other



41. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect medication errors?

Survey Responses	# Responses	% Responses
Decrease medication errors	651	79.2%
Not applicable	101	12.3%
No effect on the number of medication errors	49	6.0%
No opinion	16	1.9%
Increase medication errors	5	0.6%
Total	**822**	**100.0%**

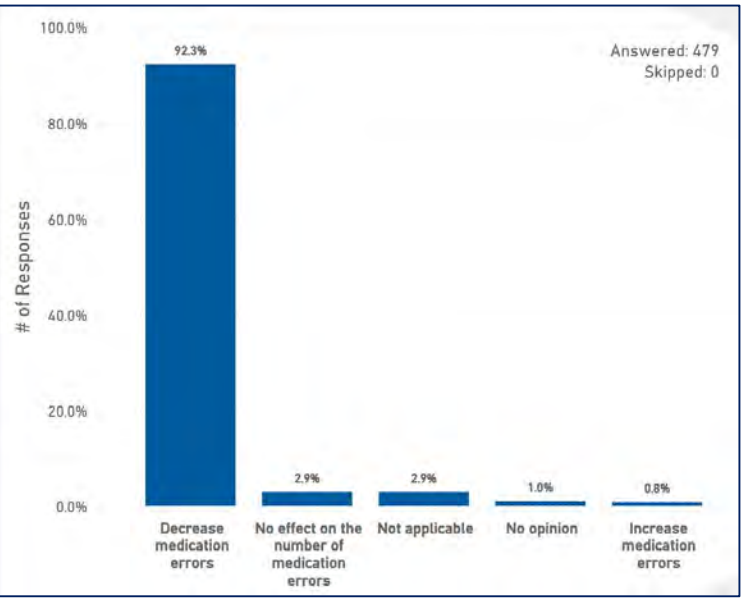
All Responses



41. In your opinion, how would an increase in the number of pharmacists in your primary practice setting affect medication errors?

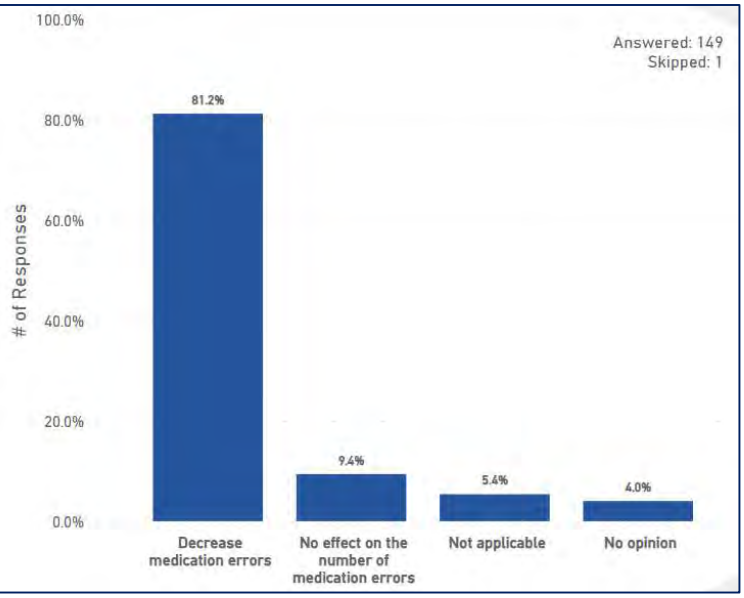
Survey Responses	# Responses	% Responses
Decrease medication errors	442	92.3%
No effect on the number of medication errors	14	2.9%
Not applicable	14	2.9%
No opinion	5	1.0%
Increase medication errors	4	0.8%
Total	**479**	**100.0%**

Retail Chain Pharmacist



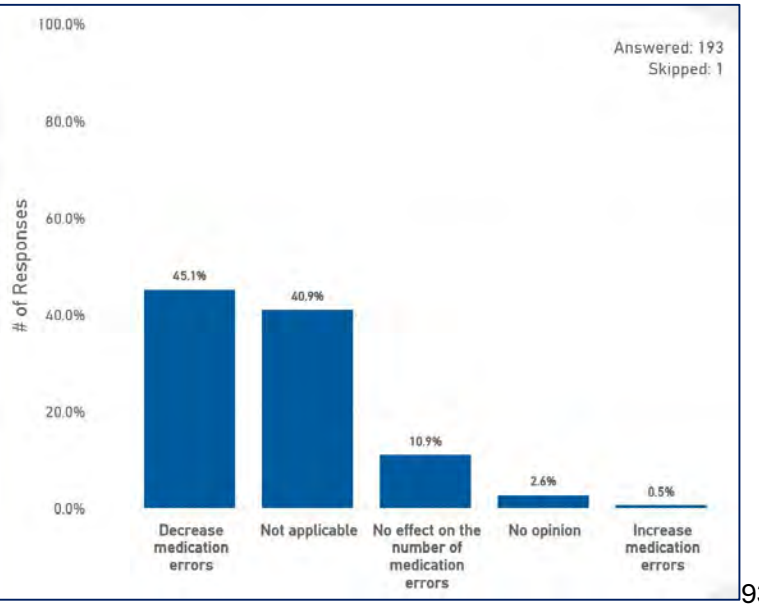
Survey Responses	# Responses	% Responses
Decrease medication errors	121	81.2%
No effect on the number of medication errors	14	9.4%
Not applicable	8	5.4%
No opinion	6	4.0%
Total	**149**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Decrease medication errors	87	45.1%
Not applicable	79	40.9%
No effect on the number of medication errors	21	10.9%
No opinion	5	2.6%
Increase medication errors	1	0.5%
Total	**193**	**100.0%**

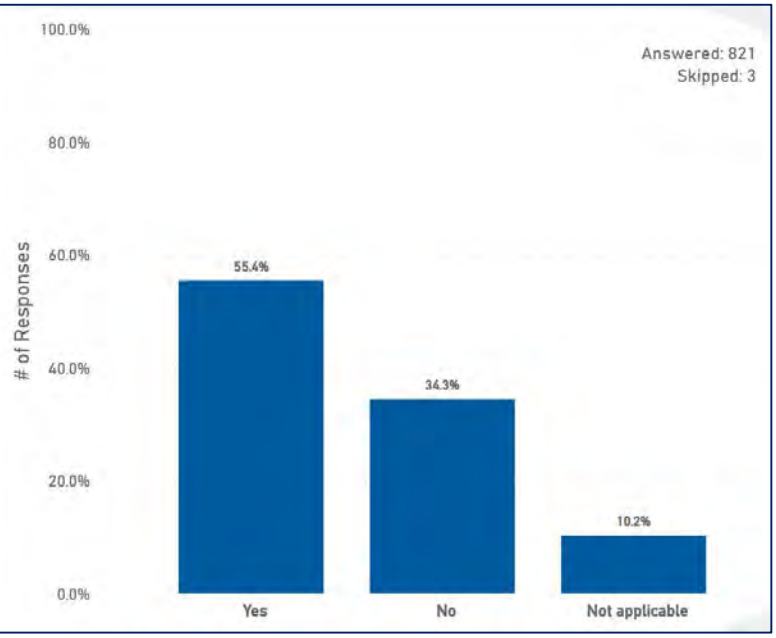
Other



42. In your opinion, is your primary practice setting a safe work environment that prioritizes patient care and safety?

Survey Responses	# Responses	% Responses
Yes	455	55.4%
No	282	34.3%
Not applicable	84	10.2%
Total	**821**	**100.0%**

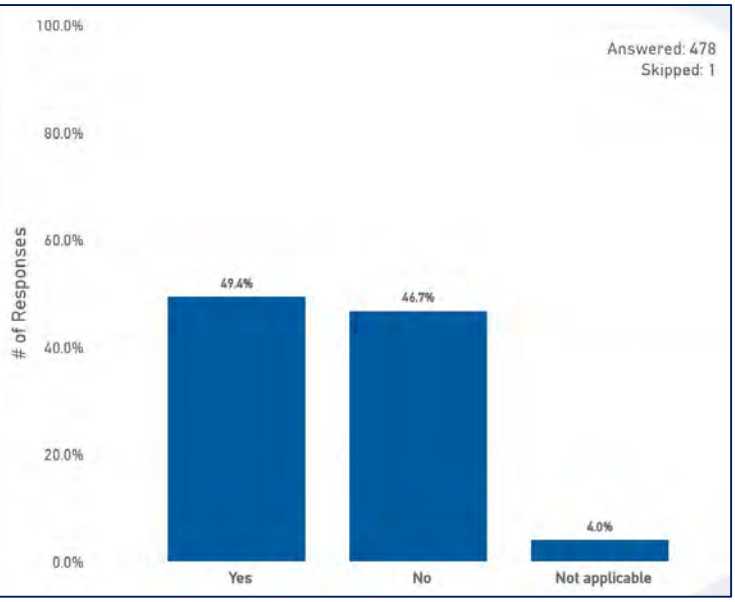
All Responses



42. In your opinion, is your primary practice setting a safe work environment that prioritizes patient care and safety?

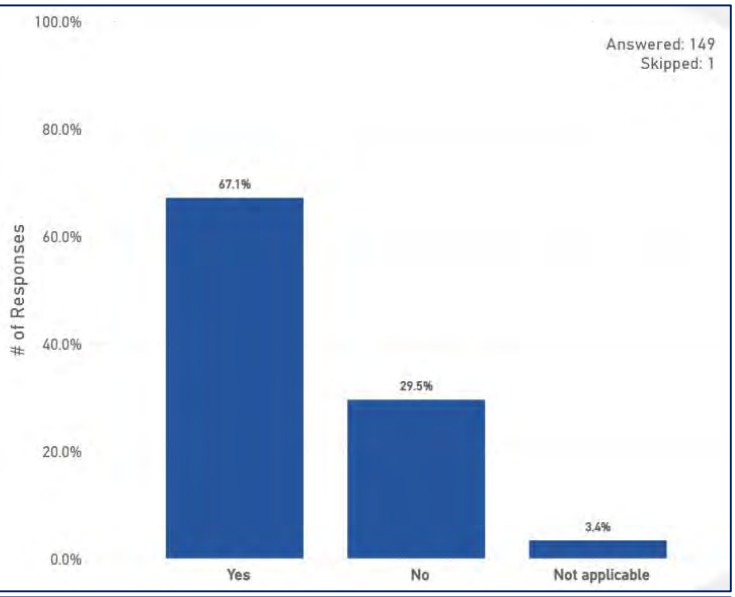
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	236	49.4%
No	223	46.7%
Not applicable	19	4.0%
Total	**478**	**100.0%**



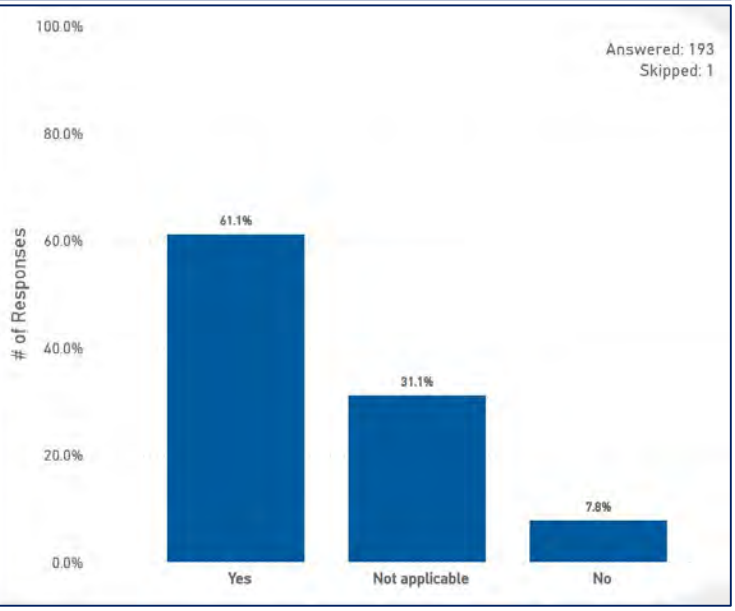
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	100	67.1%
No	44	29.5%
Not applicable	5	3.4%
Total	**149**	**100.0%**



Other

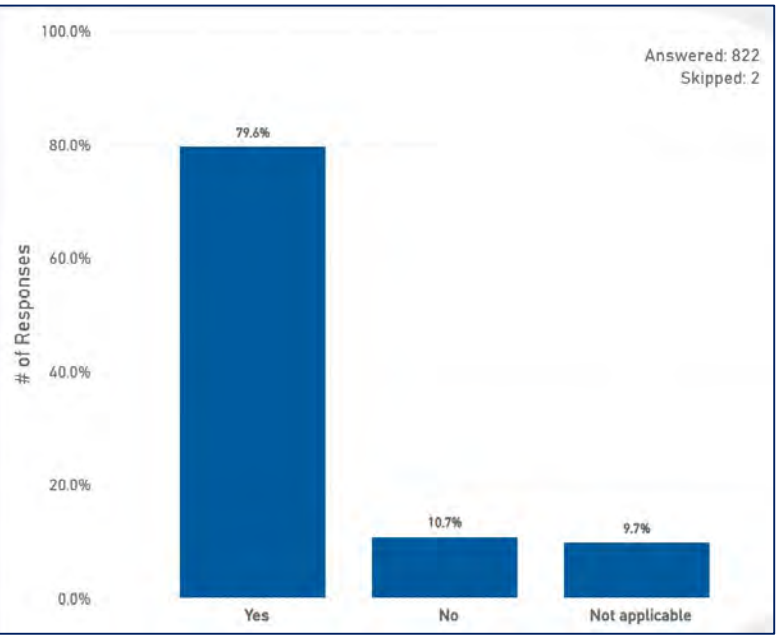
Survey Responses	# Responses	% Responses
Yes	118	61.1%
Not applicable	60	31.1%
No	15	7.8%
Total	**193**	**100.0%**



43. Does your pharmacy employer provide you with meal periods and rest periods?

Survey Responses	# Responses	% Responses
Yes	654	79.6%
No	88	10.7%
Not applicable	80	9.7%
Total	**822**	**100.0%**

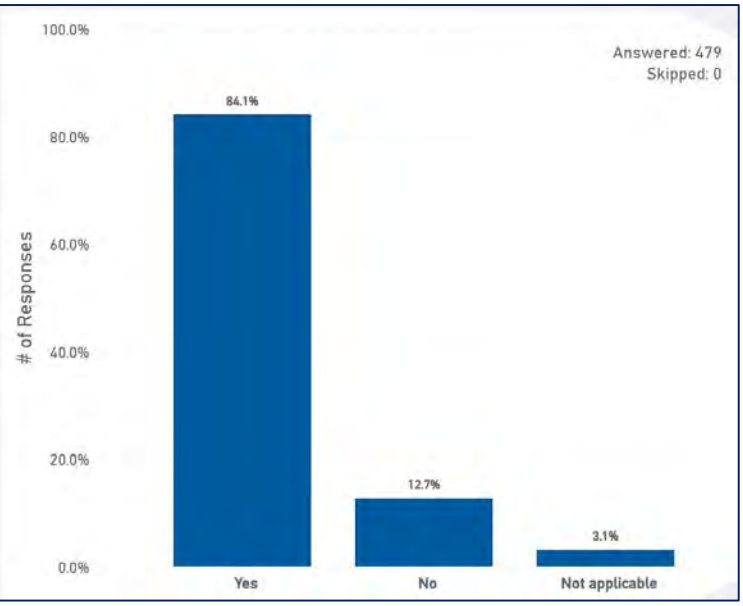
All Responses



43. Does your pharmacy employer provide you with meal periods and rest periods?

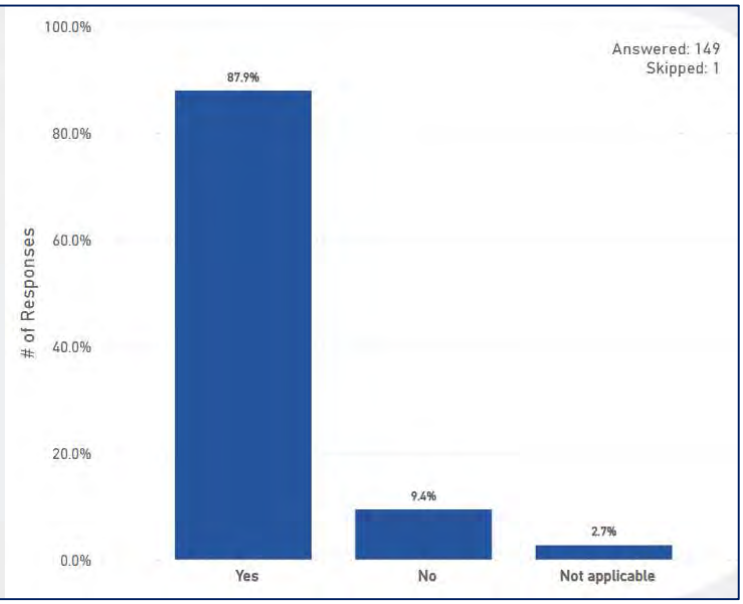
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	403	84.1%
No	61	12.7%
Not applicable	15	3.1%
Total	**479**	**100.0%**



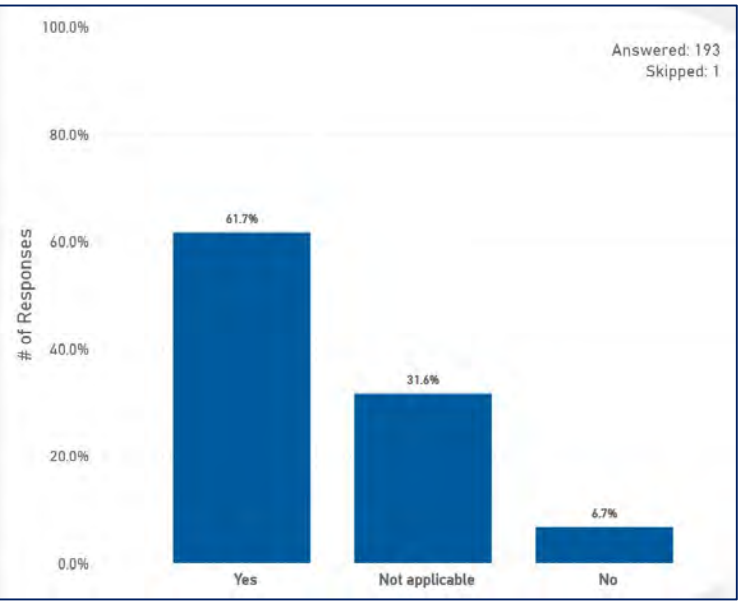
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	131	87.9%
No	14	9.4%
Not applicable	4	2.7%
Total	**149**	**100.0%**



Other

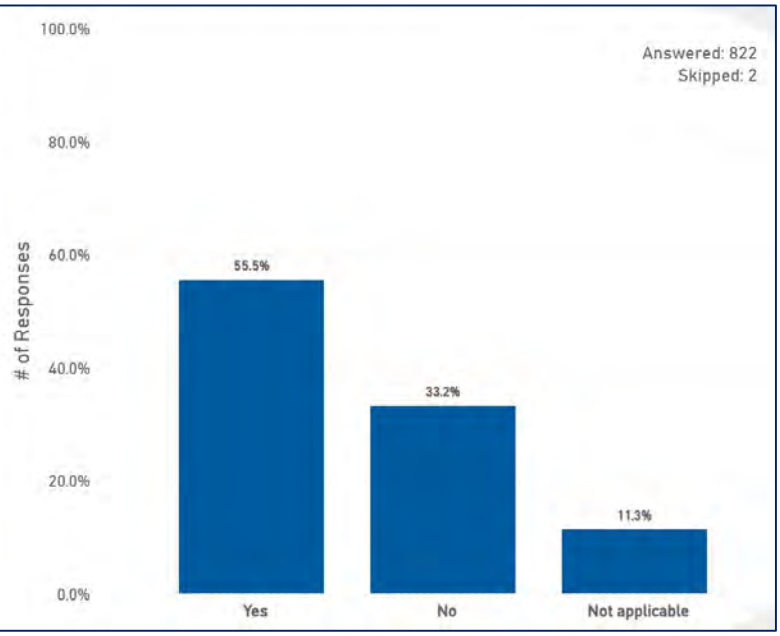
Survey Responses	# Responses	% Responses
Yes	119	61.7%
Not applicable	61	31.6%
No	13	6.7%
Total	**193**	**100.0%**



44. Are your meal periods and rest periods uninterrupted?

Survey Responses	# Responses	% Responses
Yes	456	55.5%
No	273	33.2%
Not applicable	93	11.3%
Total	**822**	**100.0%**

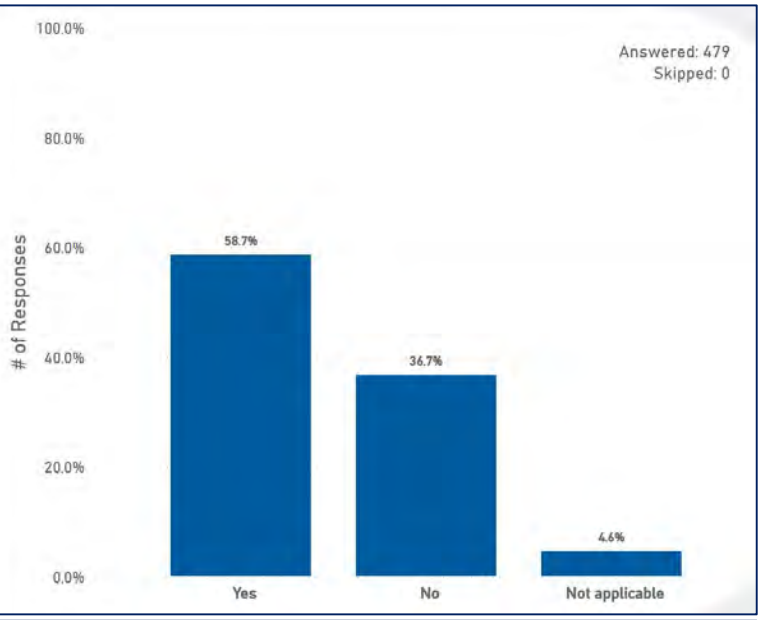
All Responses



44. Are your meal periods and rest periods uninterrupted?

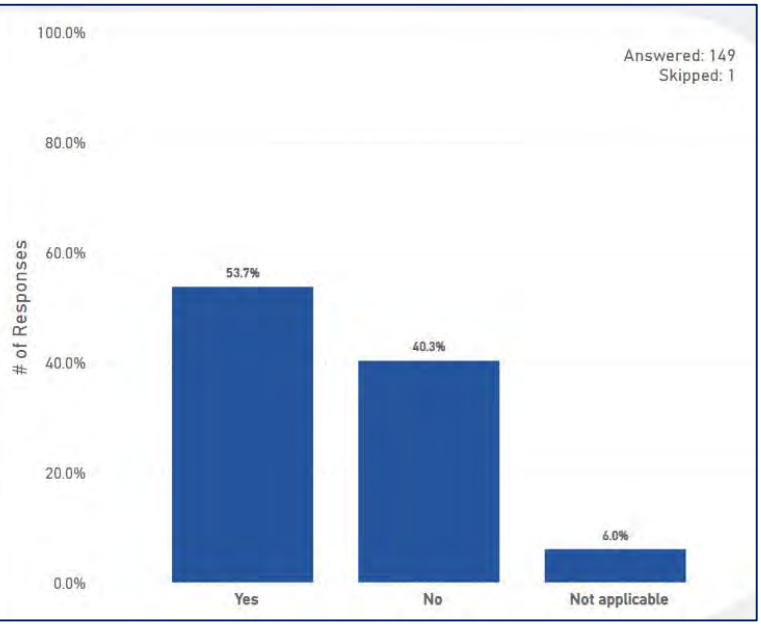
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	281	58.7%
No	176	36.7%
Not applicable	22	4.6%
Total	**479**	**100.0%**



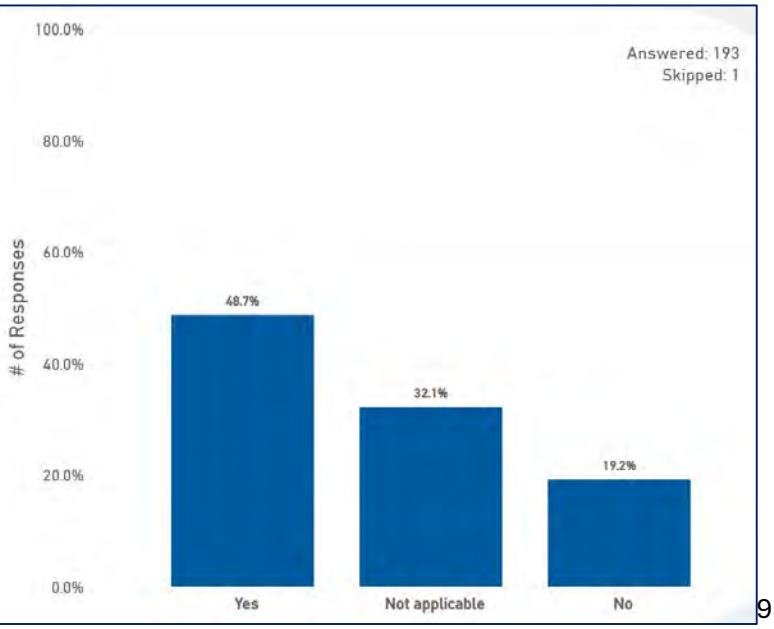
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	80	53.7%
No	60	40.3%
Not applicable	9	6.0%
Total	**149**	**100.0%**



Other

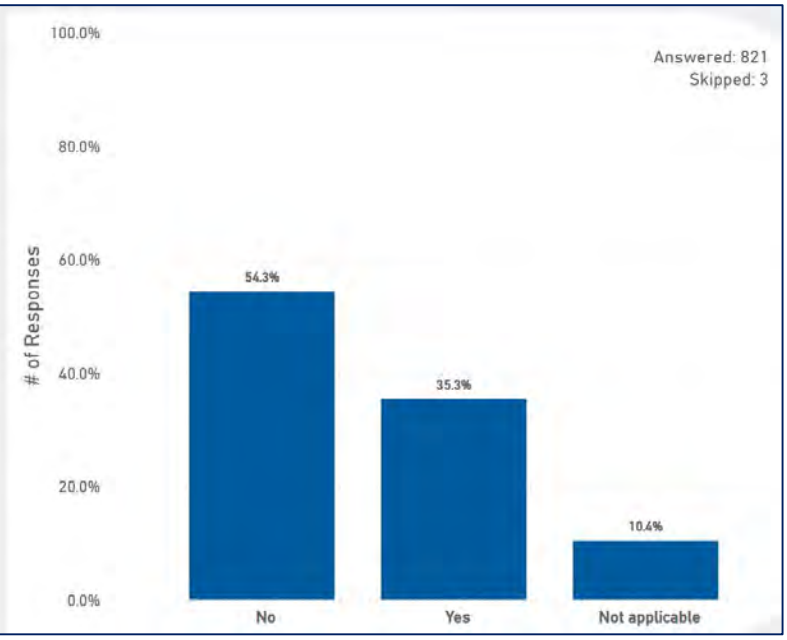
Survey Responses	# Responses	% Responses
Yes	94	48.7%
Not applicable	62	32.1%
No	37	19.2%
Total	**193**	**100.0%**



45. In your opinion, are you able to comfortably take meals and rest periods without feeling like you will fall behind or compromise patient care or safety?

Survey Responses	# Responses	% Responses
No	446	54.3%
Yes	290	35.3%
Not applicable	85	10.4%
Total	**821**	**100.0%**

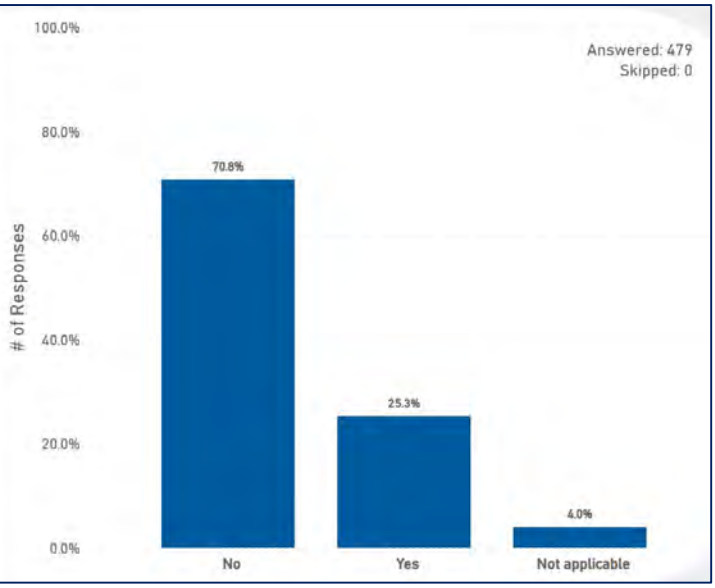
All Responses



45. In your opinion, are you able to comfortably take meals and rest periods without feeling like you will fall behind or compromise patient care or safety?

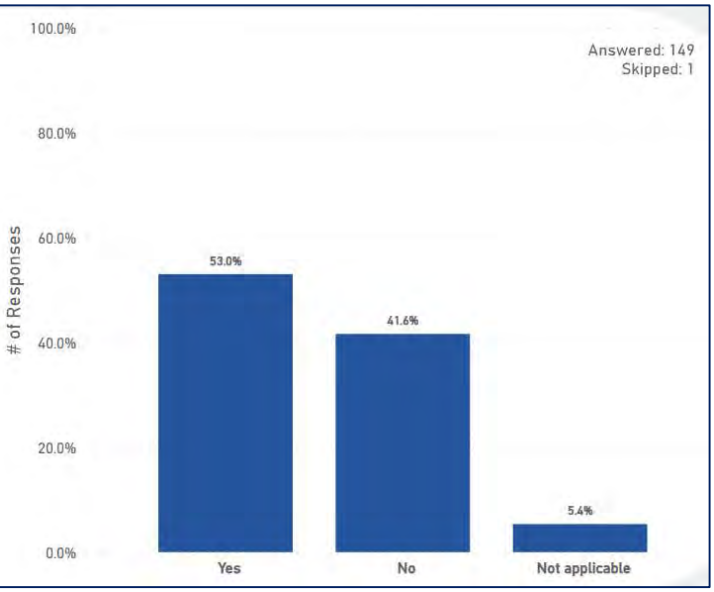
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
No	339	70.8%
Yes	121	25.3%
Not applicable	19	4.0%
Total	**479**	**100.0%**



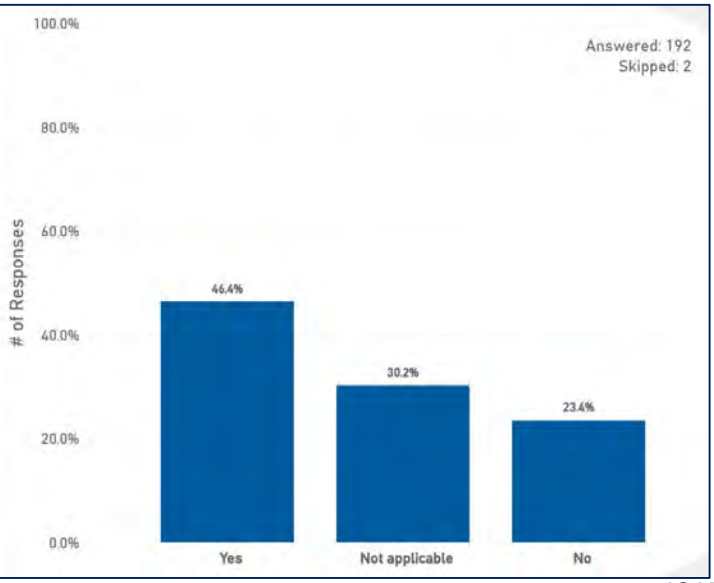
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	79	53.0%
No	62	41.6%
Not applicable	8	5.4%
Total	**149**	**100.0%**



Other

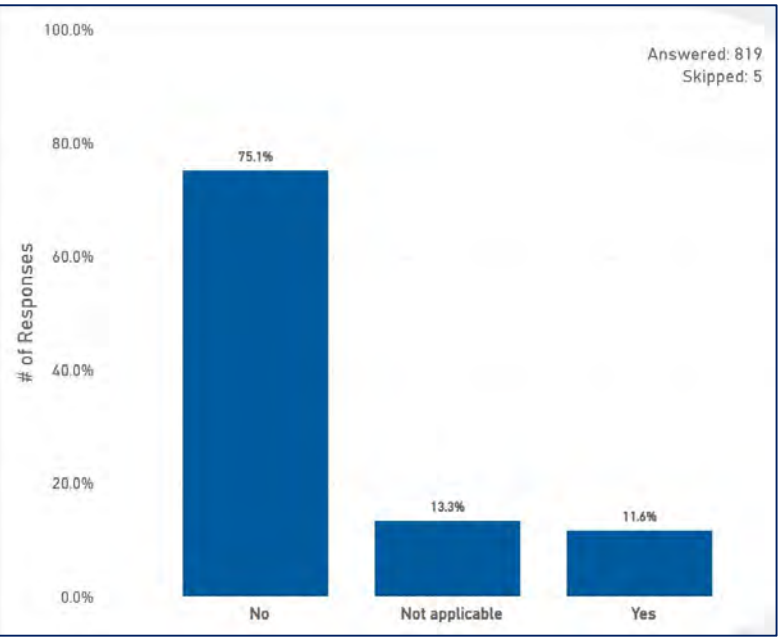
Survey Responses	# Responses	% Responses
Yes	89	46.4%
Not applicable	58	30.2%
No	45	23.4%
Total	**192**	**100.0%**



46. Did your employer require you to voluntarily agree to forego any rest period or meal period as a condition of your employment?

Survey Responses	# Responses	% Responses
No	615	75.1%
Not applicable	109	13.3%
Yes	95	11.6%
Total	**819**	**100.0%**

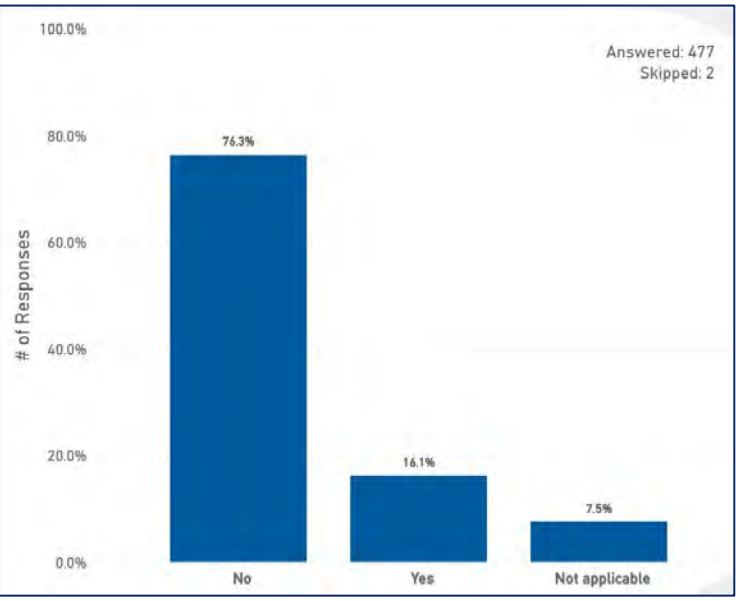
All Responses



46. Did your employer require you to voluntarily agree to forego any rest period or meal period as a condition of your employment?

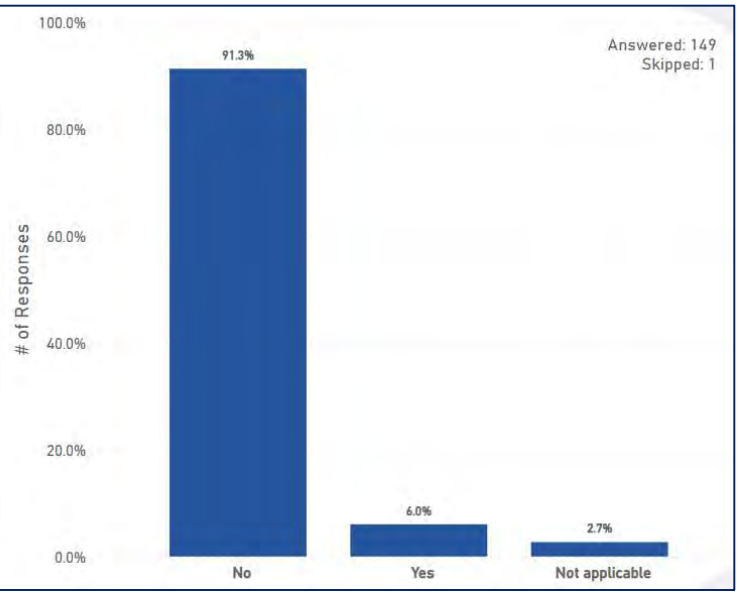
Survey Responses	# Responses	% Responses
No	364	76.3%
Yes	77	16.1%
Not applicable	36	7.5%
Total	**477**	**100.0%**

Retail Chain Pharmacist



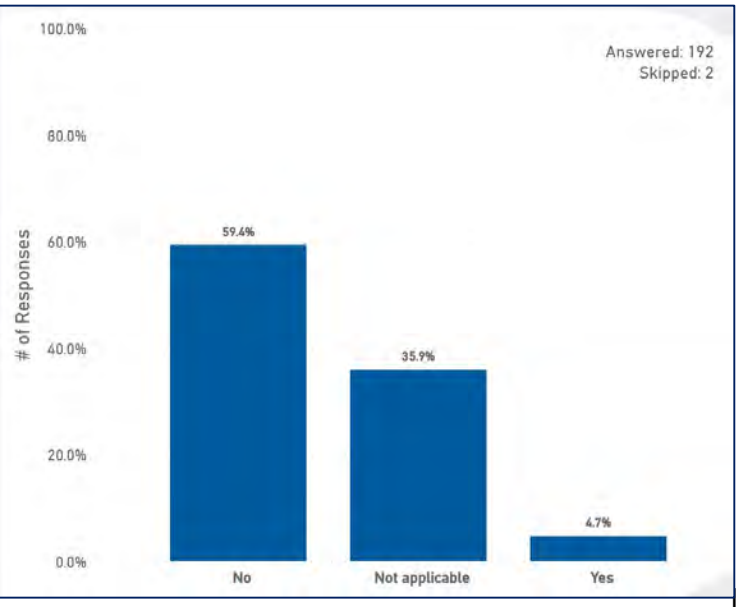
Survey Responses	# Responses	% Responses
No	136	91.3%
Yes	9	6.0%
Not applicable	4	2.7%
Total	**149**	**100.0%**

Institutional/Hospital Pharmacist



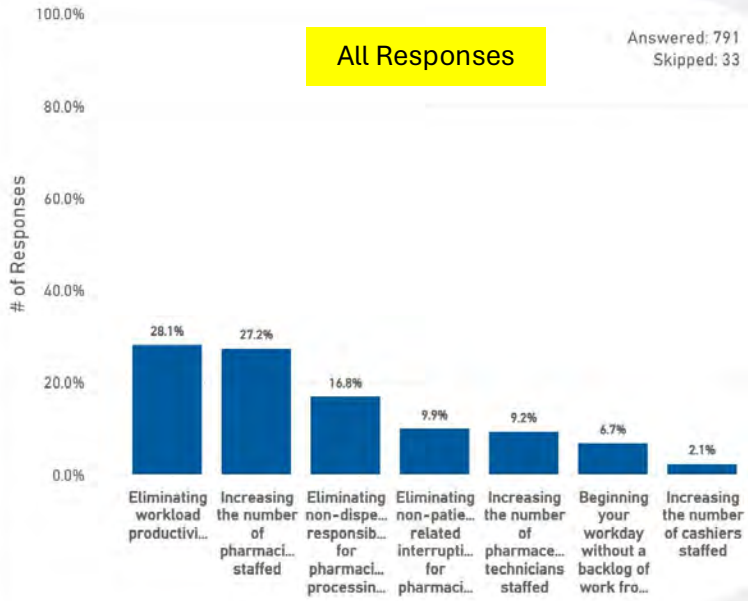
Survey Responses	# Responses	% Responses
No	114	59.4%
Not applicable	69	35.9%
Yes	9	4.7%
Total	**192**	**100.0%**

Other



47. Please rank the following from 1 to 7 on their impact on patient safety (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety). *The responses below were ranked as 1.*

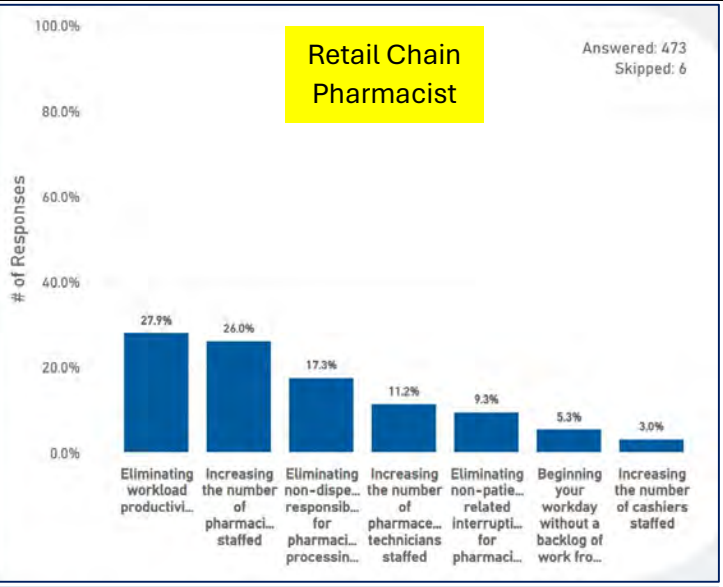
Survey Responses	# Responses	% Responses
Eliminating workload productivity	222	28.1%
Increasing the number of pharmacists staffed	215	27.2%
Eliminating non-dispensing responsibilities for pharmacists processing prescriptions	133	16.8%
Eliminating non-patient related interruptions for pharmacists processing prescriptions	78	9.9%
Increasing the number of pharmaceutical technicians staffed	73	9.2%
Beginning your workday without a backlog of work from the previous shift or day	53	6.7%
Increasing the number of cashiers staffed	17	2.1%
Total	**791**	**100.0%**



47. Please rank the following from 1 to 7 on their impact on patient safety (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety). *The responses below were ranked as 1.*

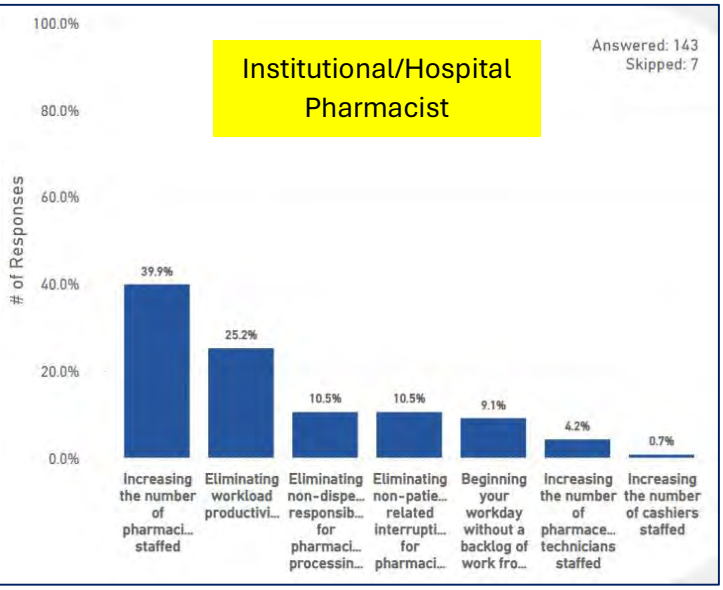
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Eliminating workload productivity	132	27.9%
Increasing the number of pharmacists staffed	123	26.0%
Eliminating non-dispensing responsibilities for pharmacists processing prescriptions	82	17.3%
Increasing the number of pharmaceutical technicians staffed	53	11.2%
Eliminating non-patient related interruptions for pharmacists processing prescriptions	44	9.3%
Beginning your workday without a backlog of work from the previous shift or day	25	5.3%
Increasing the number of cashiers staffed	14	3.0%
Total	**473**	**100.0%**



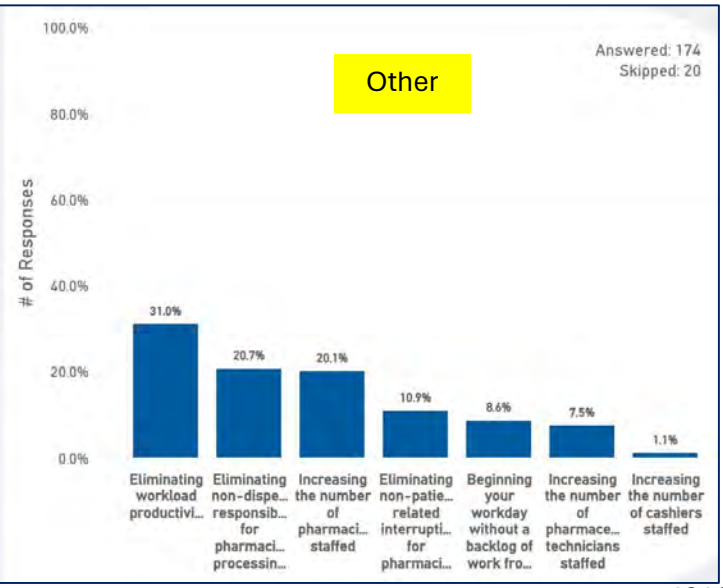
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Increasing the number of pharmacists staffed	57	39.9%
Eliminating workload productivity	36	25.2%
Eliminating non-dispensing responsibilities for pharmacists processing prescriptions	15	10.5%
Eliminating non-patient related interruptions for pharmacists processing prescriptions	15	10.5%
Beginning your workday without a backlog of work from the previous shift or day	13	9.1%
Increasing the number of pharmaceutical technicians staffed	6	4.2%
Increasing the number of cashiers staffed	1	0.7%
Total	**143**	**100.0%**



Other

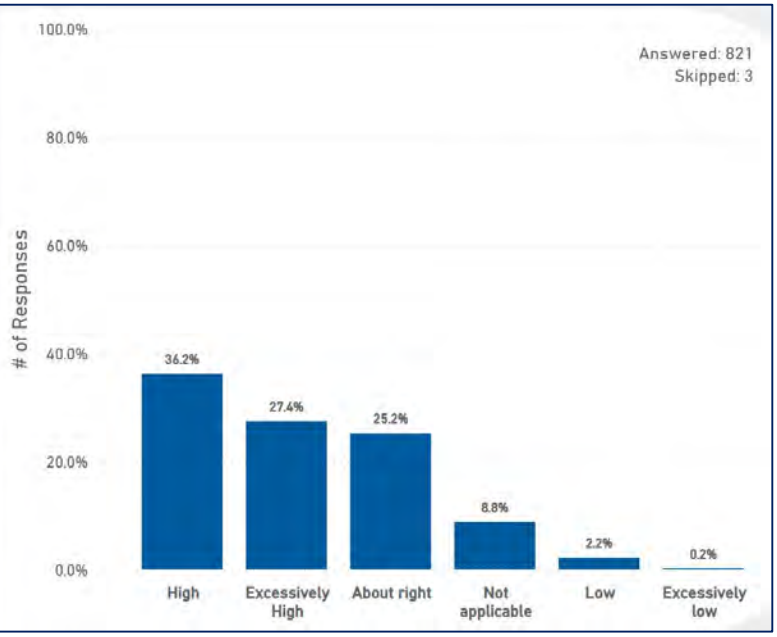
Survey Responses	# Responses	% Responses
Eliminating workload productivity	54	31.0%
Eliminating non-dispensing responsibilities for pharmacists processing prescriptions	36	20.7%
Increasing the number of pharmacists staffed	35	20.1%
Eliminating non-patient related interruptions for pharmacists processing prescriptions	19	10.9%
Beginning your workday without a backlog of work from the previous shift or day	15	8.6%
Increasing the number of pharmaceutical technicians staffed	13	7.5%
Increasing the number of cashiers staffed	2	1.1%
Total	**174**	**100.0%**



48. My current workload is:

Survey Responses	# Responses	% Responses
High	297	36.2%
Excessively High	225	27.4%
About right	207	25.2%
Not applicable	72	8.8%
Low	18	2.2%
Excessively low	2	0.2%
Total	**821**	**100.0%**

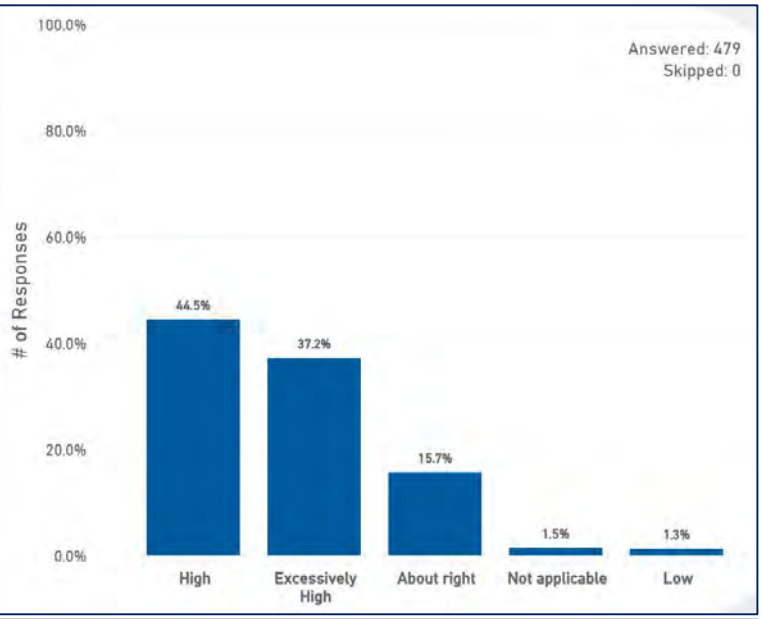
All Responses



48. My current workload is:

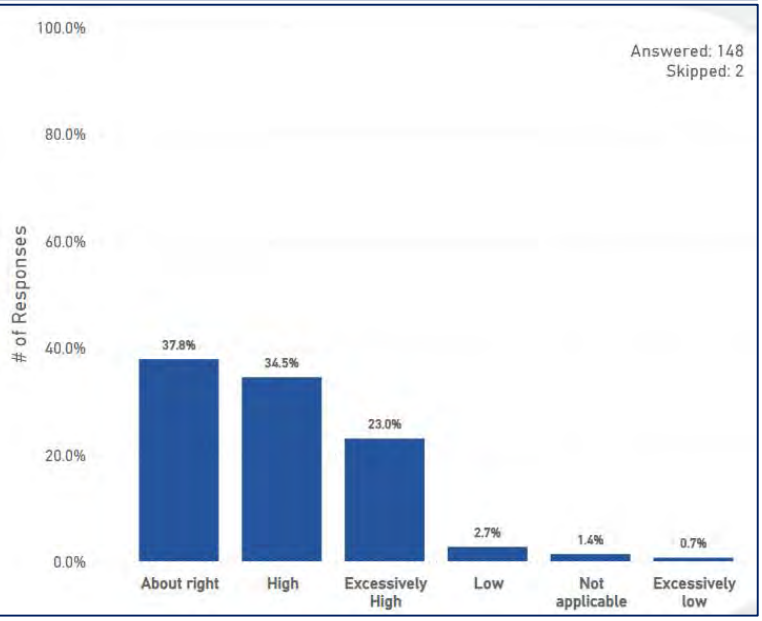
Survey Responses	# Responses	% Responses
High	213	44.5%
Excessively High	178	37.2%
About right	75	15.7%
Not applicable	7	1.5%
Low	6	1.3%
Total	**479**	**100.0%**

Retail Chain Pharmacist



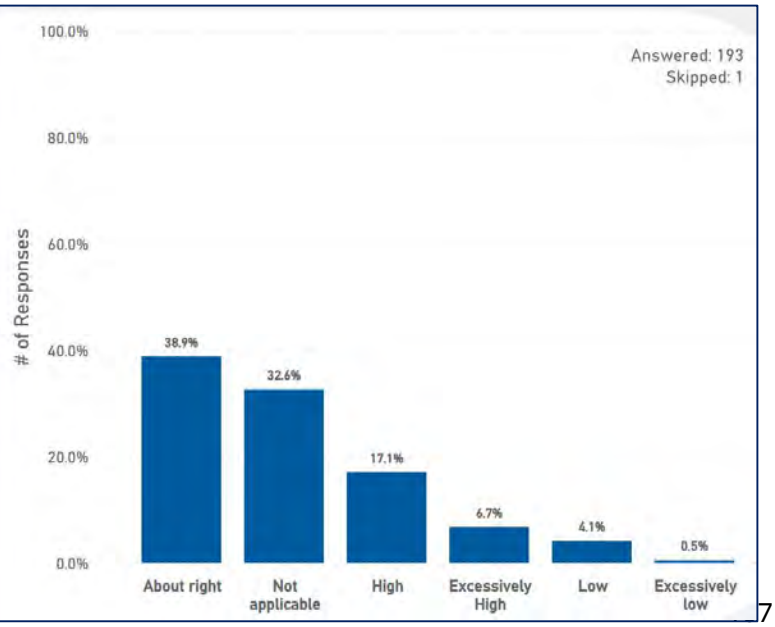
Survey Responses	# Responses	% Responses
About right	56	37.8%
High	51	34.5%
Excessively High	34	23.0%
Low	4	2.7%
Not applicable	2	1.4%
Excessively low	1	0.7%
Total	**148**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
About right	75	38.9%
Not applicable	63	32.6%
High	33	17.1%
Excessively High	13	6.7%
Low	8	4.1%
Excessively low	1	0.5%
Total	**193**	**100.0%**

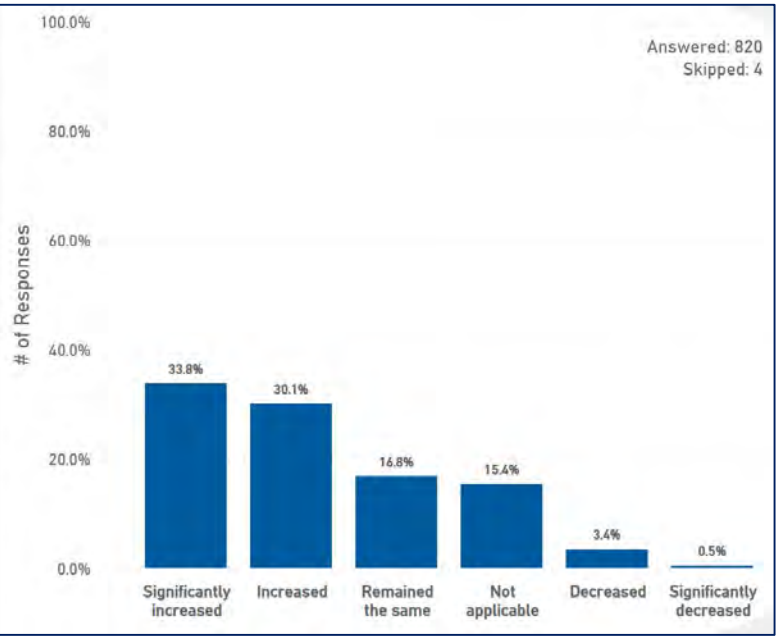
Other



49. Compared to pre-pandemic, my workload has:

Survey Responses	# Responses	% Responses
Significantly increased	277	33.8%
Increased	247	30.1%
Remained the same	138	16.8%
Not applicable	126	15.4%
Decreased	28	3.4%
Significantly decreased	4	0.5%
Total	**820**	**100.0%**

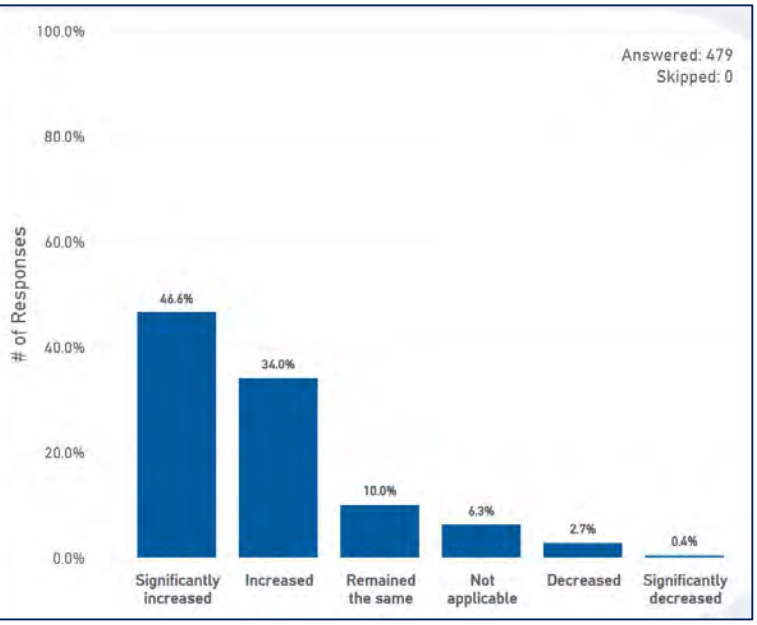
All Responses



49. Compared to pre-pandemic, my workload has:

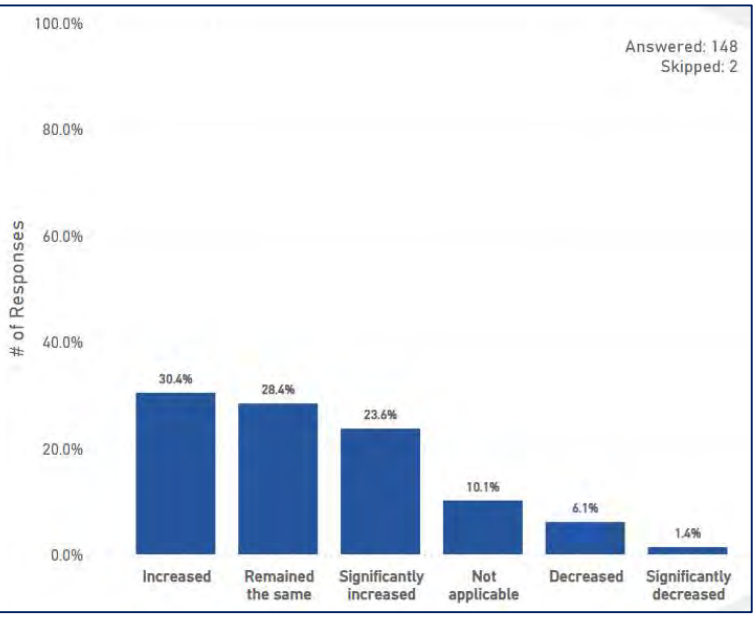
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Significantly increased	223	46.6%
Increased	163	34.0%
Remained the same	48	10.0%
Not applicable	30	6.3%
Decreased	13	2.7%
Significantly decreased	2	0.4%
Total	**479**	**100.0%**



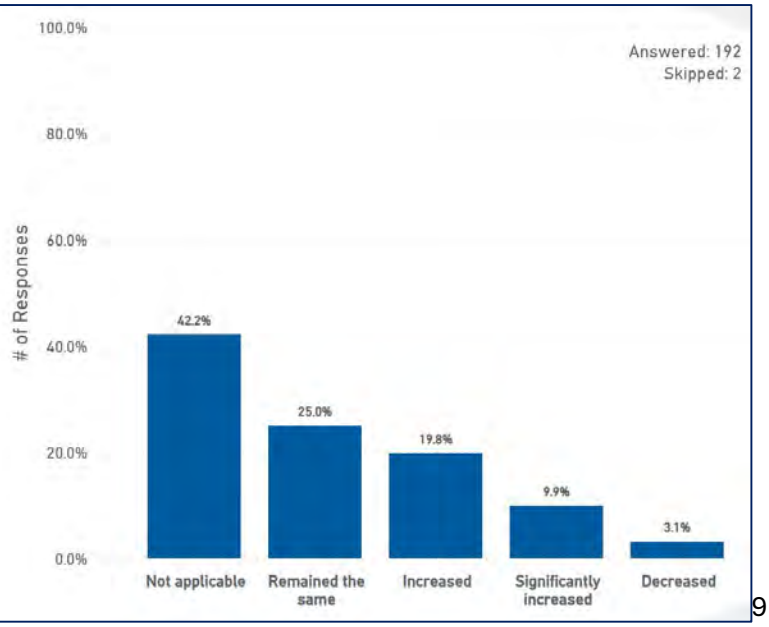
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Increased	45	30.4%
Remained the same	42	28.4%
Significantly increased	35	23.6%
Not applicable	15	10.1%
Decreased	9	6.1%
Significantly decreased	2	1.4%
Total	**148**	**100.0%**



Other

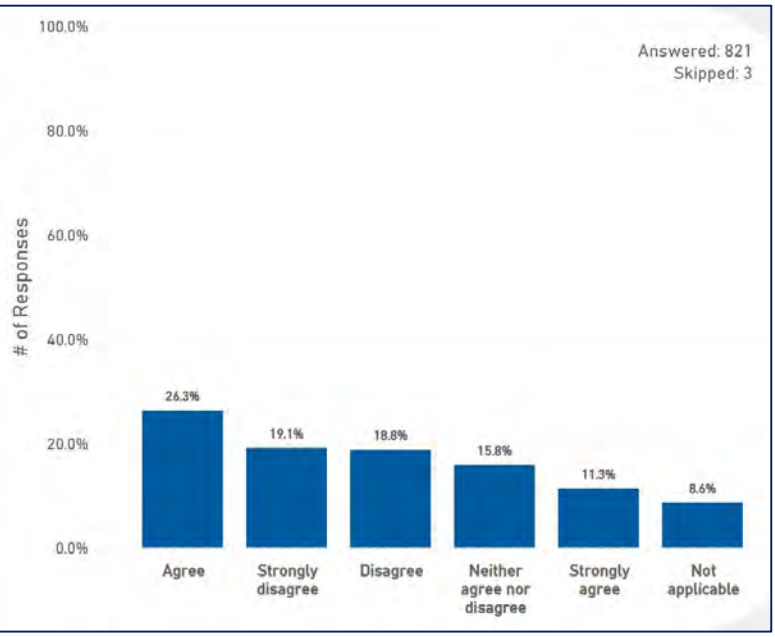
Survey Responses	# Responses	% Responses
Not applicable	81	42.2%
Remained the same	48	25.0%
Increased	38	19.8%
Significantly increased	19	9.9%
Decreased	6	3.1%
Total	**192**	**100.0%**



50. I feel my employer provides a work environment that allows for safe patient care.

Survey Responses	# Responses	% Responses
Agree	216	26.3%
Strongly disagree	157	19.1%
Disagree	154	18.8%
Neither agree nor disagree	130	15.8%
Strongly agree	93	11.3%
Not applicable	71	8.6%
Total	**821**	**100.0%**

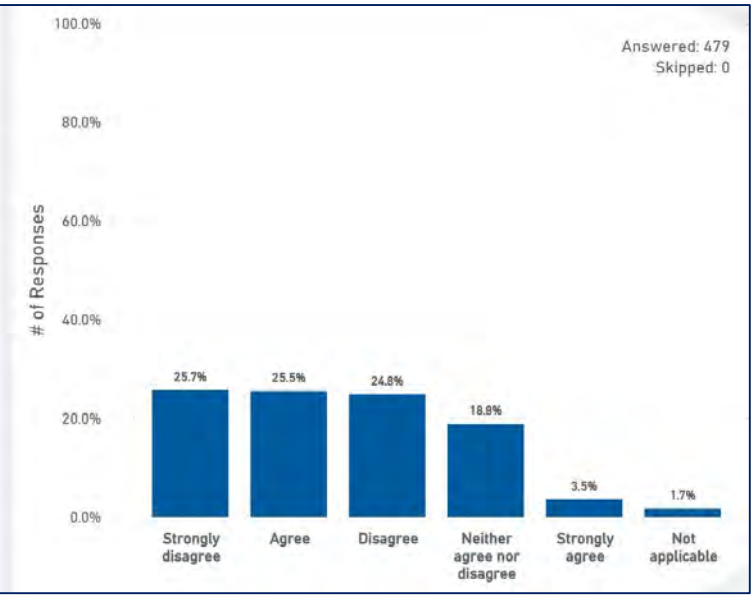
All Responses



50. I feel my employer provides a work environment that allows for safe patient care.

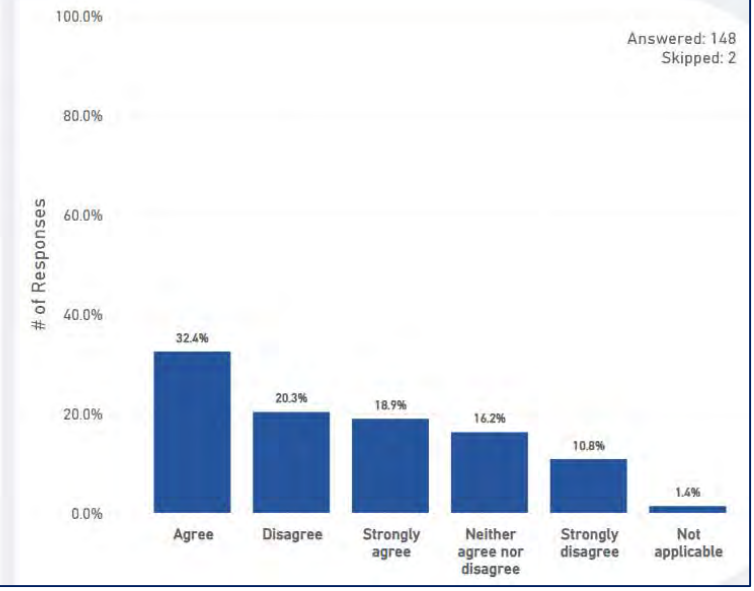
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Strongly disagree	123	25.7%
Agree	122	25.5%
Disagree	119	24.8%
Neither agree nor disagree	90	18.8%
Strongly agree	17	3.5%
Not applicable	8	1.7%
Total	**479**	**100.0%**



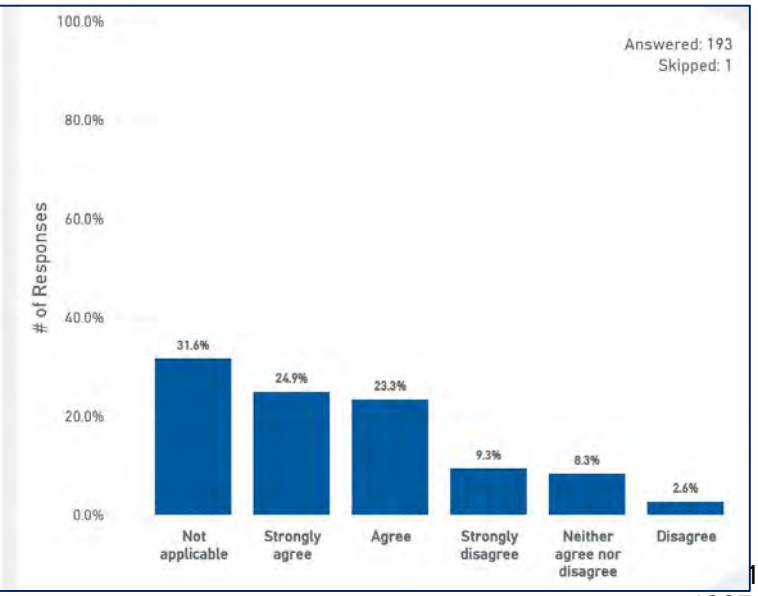
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Agree	48	32.4%
Disagree	30	20.3%
Strongly agree	28	18.9%
Neither agree nor disagree	24	16.2%
Strongly disagree	16	10.8%
Not applicable	2	1.4%
Total	**148**	**100.0%**



Other

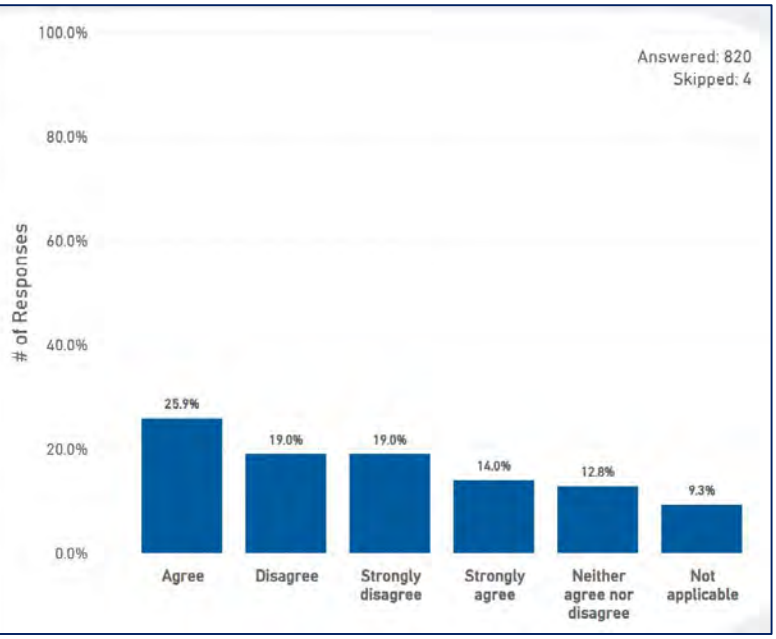
Survey Responses	# Responses	% Responses
Not applicable	61	31.6%
Strongly agree	48	24.9%
Agree	45	23.3%
Strongly disagree	18	9.3%
Neither agree nor disagree	16	8.3%
Disagree	5	2.6%
Total	**193**	**100.0%**



51. I feel safe voicing any workplace concerns to my employer.

Survey Responses	# Responses	% Responses
Agree	212	25.9%
Disagree	156	19.0%
Strongly disagree	156	19.0%
Strongly agree	115	14.0%
Neither agree nor disagree	105	12.8%
Not applicable	76	9.3%
Total	**820**	**100.0%**

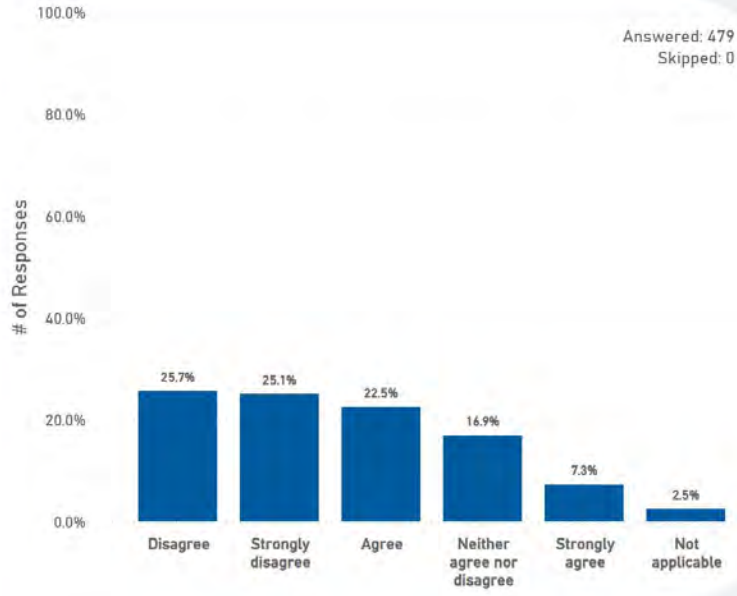
All Responses



51. I feel safe voicing any workplace concerns to my employer.

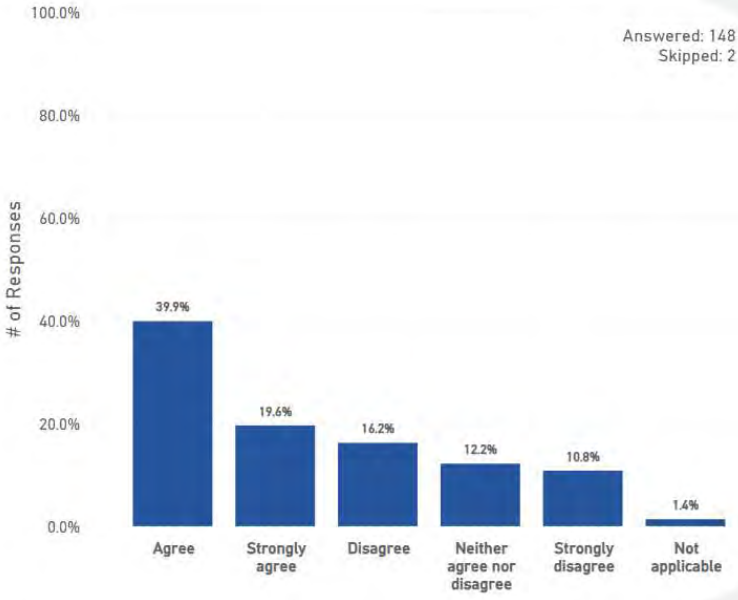
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Disagree	123	25.7%
Strongly disagree	120	25.1%
Agree	108	22.5%
Neither agree nor disagree	81	16.9%
Strongly agree	35	7.3%
Not applicable	12	2.5%
Total	**479**	**100.0%**



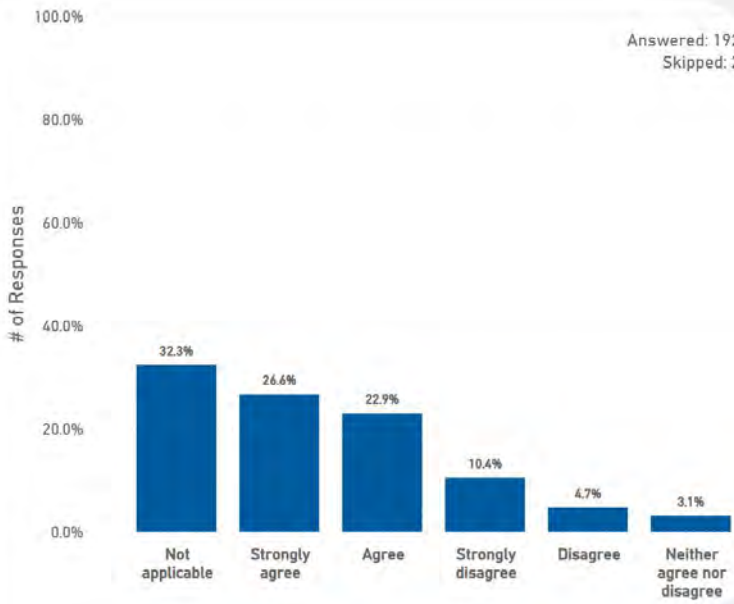
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Agree	59	39.9%
Strongly agree	29	19.6%
Disagree	24	16.2%
Neither agree nor disagree	18	12.2%
Strongly disagree	16	10.8%
Not applicable	2	1.4%
Total	**148**	**100.0%**



Other

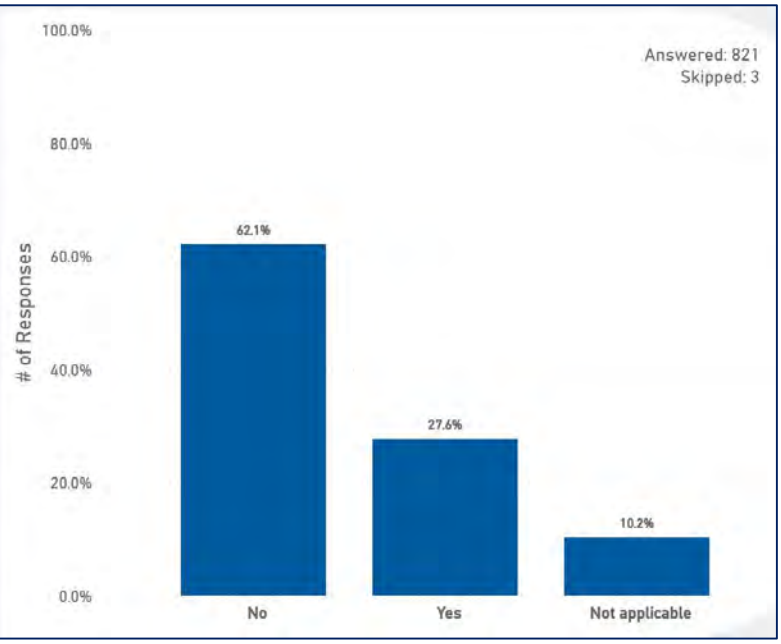
Survey Responses	# Responses	% Responses
Not applicable	62	32.3%
Strongly agree	51	26.6%
Agree	44	22.9%
Strongly disagree	20	10.4%
Disagree	9	4.7%
Neither agree nor disagree	6	3.1%
Total	**192**	**100.0%**



52. Have you quit or left a pharmacy employment due to patient safety concerns?

Survey Responses	# Responses	% Responses
No	510	62.1%
Yes	227	27.6%
Not applicable	84	10.2%
Total	**821**	**100.0%**

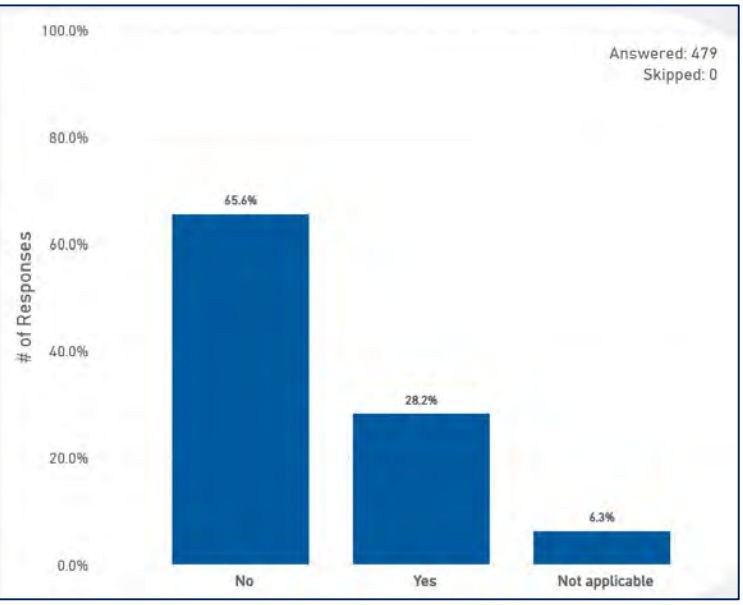
All Responses



52. Have you quit or left a pharmacy employment due to patient safety concerns?

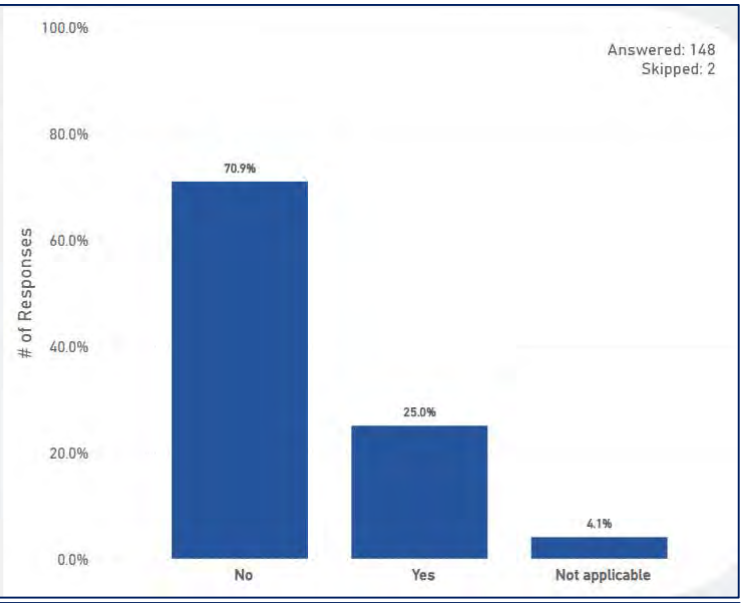
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
No	314	65.6%
Yes	135	28.2%
Not applicable	30	6.3%
Total	**479**	**100.0%**



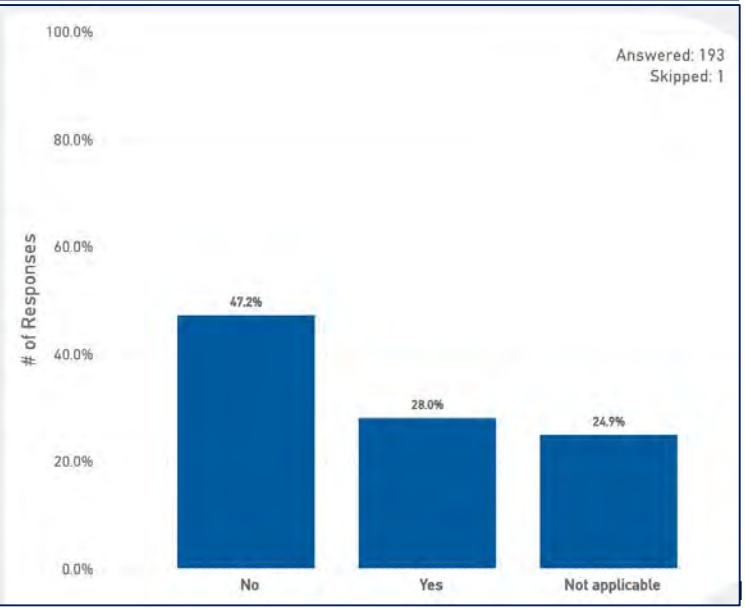
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
No	105	70.9%
Yes	37	25.0%
Not applicable	6	4.1%
Total	**148**	**100.0%**



Other

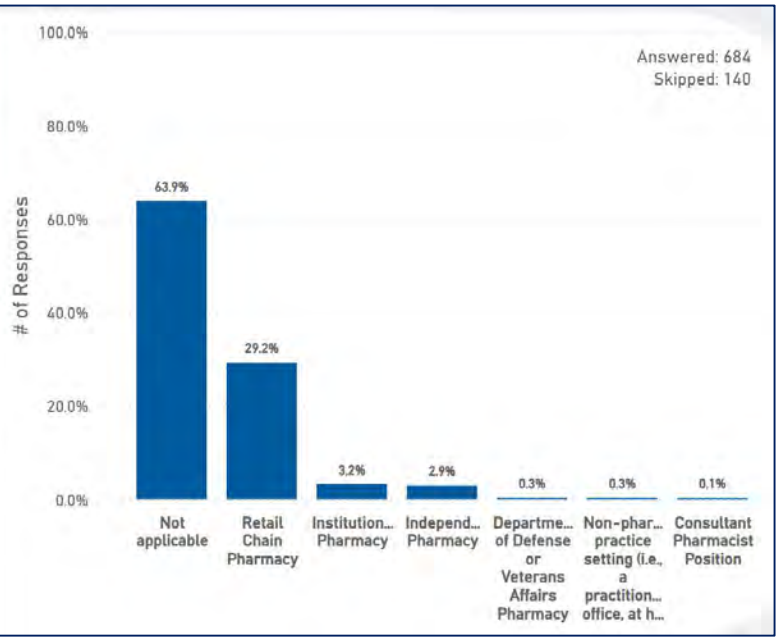
Survey Responses	# Responses	% Responses
No	91	47.2%
Yes	54	28.0%
Not applicable	48	24.9%
Total	**193**	**100.0%**



53. If you answered “yes” to question 52, what pharmacy practice setting did you leave?

Survey Responses	# Responses	% Responses
Not applicable	437	63.9%
Retail Chain Pharmacy	200	29.2%
Institutional/Hospital Pharmacy	22	3.2%
Independent Pharmacy	20	2.9%
Department of Defense or Veterans Affairs Pharmacy	2	0.3%
Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)	2	0.3%
Consultant Pharmacist Position	1	0.1%
Total	**684**	**100.0%**

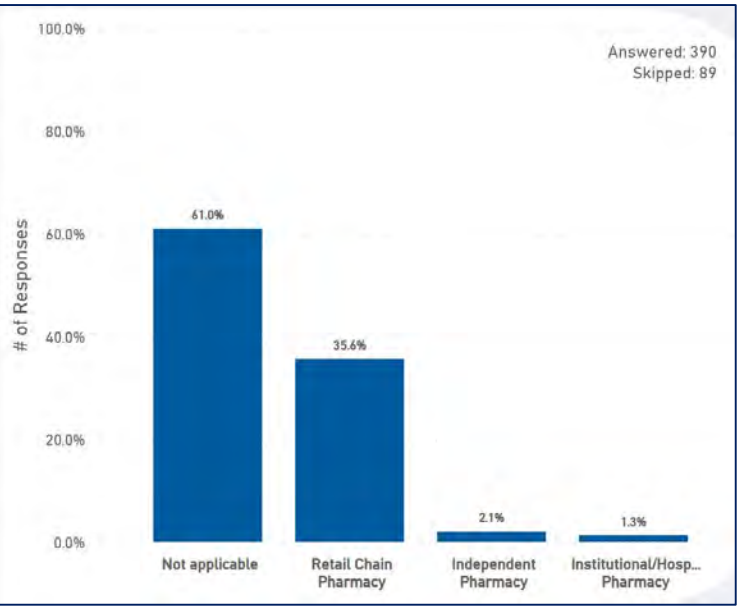
All Responses



53. If you answered “yes” to question 52, what pharmacy practice setting did you leave?

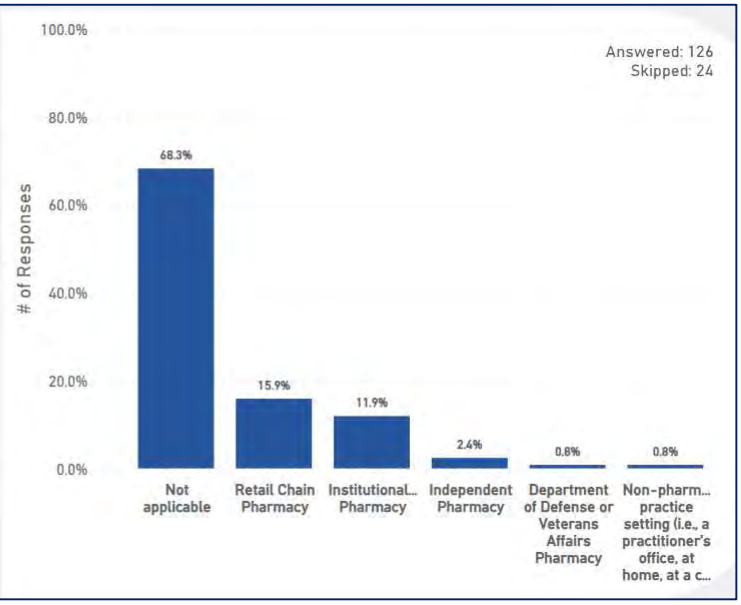
Survey Responses	# Responses	% Responses
Not applicable	238	61.0%
Retail Chain Pharmacy	139	35.6%
Independent Pharmacy	8	2.1%
Institutional/Hospital Pharmacy	5	1.3%
Total	**390**	**100.0%**

Retail Chain Pharmacist



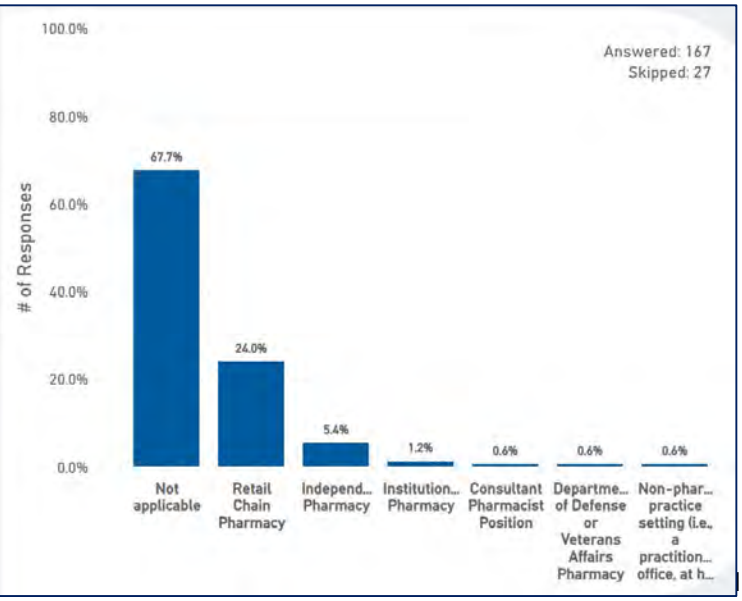
Survey Responses	# Responses	% Responses
Not applicable	86	68.3%
Retail Chain Pharmacy	20	15.9%
Institutional/Hospital Pharmacy	15	11.9%
Independent Pharmacy	3	2.4%
Department of Defense or Veterans Affairs Pharmacy	1	0.8%
Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)	1	0.8%
Total	**126**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Not applicable	113	67.7%
Retail Chain Pharmacy	40	24.0%
Independent Pharmacy	9	5.4%
Institutional/Hospital Pharmacy	2	1.2%
Consultant Pharmacist Position	1	0.6%
Department of Defense or Veterans Affairs Pharmacy	1	0.6%
Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)	1	0.6%
Total	**167**	**100.0%**

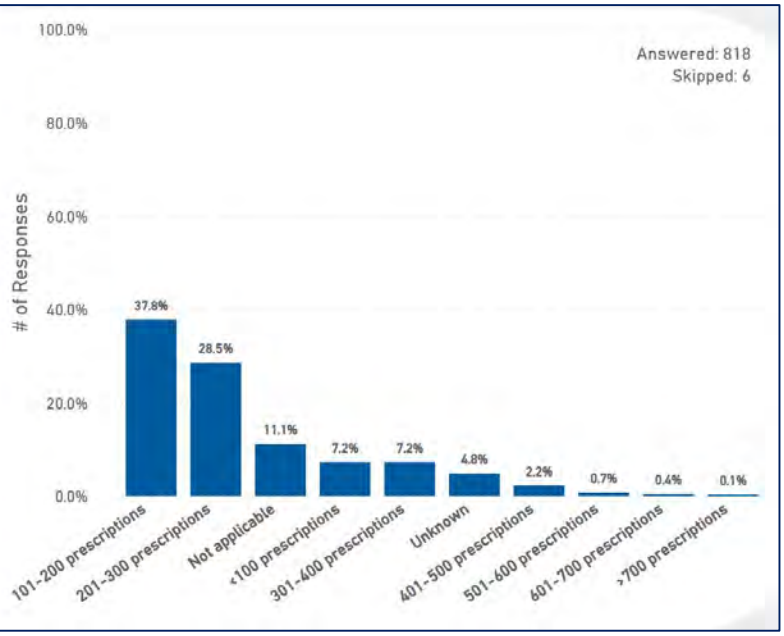
Other



54. In your opinion, what is the number of prescriptions ONE pharmacist should be able to reasonably and safely fill on a given weekday, working from 9am to 7pm, in a general retail pharmacy setting, with the assistance of one to three pharmaceutical technicians or pharmaceutical technicians in training IF non-dispensing services such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects ARE EXCLUDED?

Survey Responses	# Responses	% Responses
101-200 prescriptions	309	37.8%
201-300 prescriptions	233	28.5%
Not applicable	91	11.1%
<100 prescriptions	59	7.2%
301-400 prescriptions	59	7.2%
Unknown	39	4.8%
401-500 prescriptions	18	2.2%
501-600 prescriptions	6	0.7%
601-700 prescriptions	3	0.4%
>700 prescriptions	1	0.1%
Total	**818**	**100.0%**

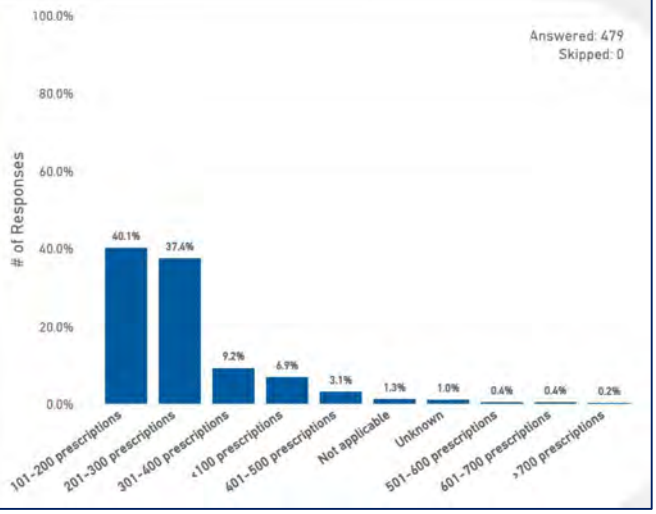
All Responses



54. In your opinion, what is the number of prescriptions ONE pharmacist should be able to reasonably and safely fill on a given weekday, working from 9am to 7pm, in a general retail pharmacy setting, with the assistance of one to three pharmaceutical technicians or pharmaceutical technicians in training IF non-dispensing services such as medication therapy management, vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects ARE EXCLUDED?

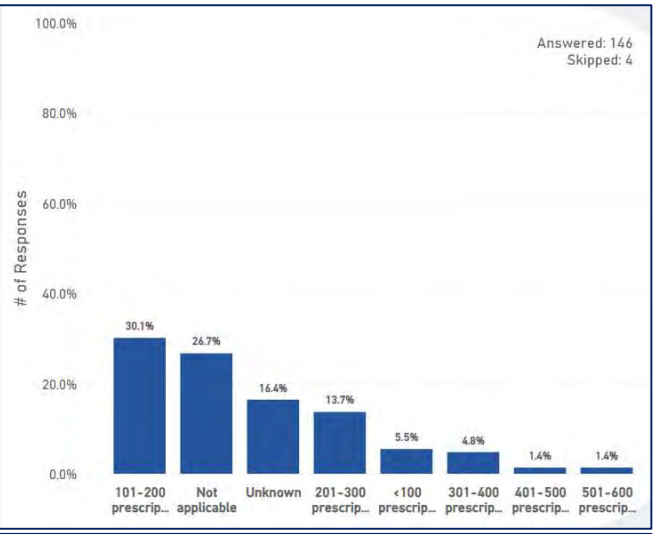
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
101-200 prescriptions	192	40.1%
201-300 prescriptions	179	37.4%
301-400 prescriptions	44	9.2%
<100 prescriptions	33	6.9%
401-500 prescriptions	15	3.1%
Not applicable	6	1.3%
Unknown	5	1.0%
501-600 prescriptions	2	0.4%
601-700 prescriptions	2	0.4%
>700 prescriptions	1	0.2%
Total	**479**	**100.0%**



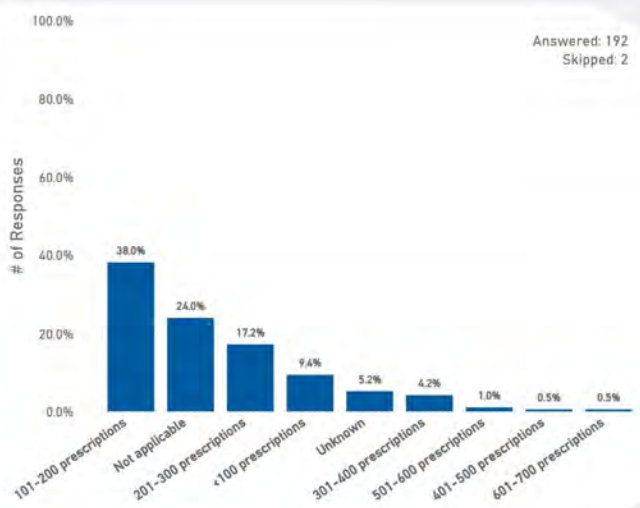
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
101-200 prescriptions	44	30.1%
Not applicable	39	26.7%
Unknown	24	16.4%
201-300 prescriptions	20	13.7%
<100 prescriptions	8	5.5%
301-400 prescriptions	7	4.8%
401-500 prescriptions	2	1.4%
501-600 prescriptions	2	1.4%
Total	**146**	**100.0%**



Other

Survey Responses	# Responses	% Responses
101-200 prescriptions	73	38.0%
Not applicable	46	24.0%
201-300 prescriptions	33	17.2%
<100 prescriptions	18	9.4%
Unknown	10	5.2%
301-400 prescriptions	8	4.2%
501-600 prescriptions	2	1.0%
401-500 prescriptions	1	0.5%
601-700 prescriptions	1	0.5%
Total	**192**	**100.0%**



55. What workplace conditions, if any, do you believe should be addressed at your primary practice setting to promote patient safety? What suggestions do you have for improving the condition?

Results to this question begins on page 128.

56. What other recommendations for changes do you have that you believe would lead to improved patient care or patient safety?

Results to this question begins on page 148.

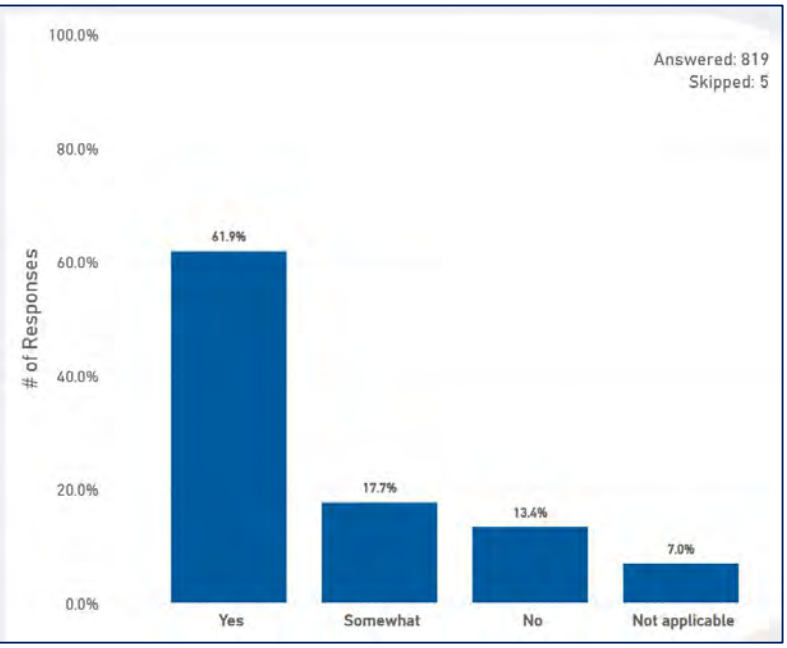
57. Please share any other comments you may have:

Results to this question begins on page 165.

58. Have you felt burned out from your work?

Survey Responses	# Responses	% Responses
Yes	507	61.9%
Somewhat	145	17.7%
No	110	13.4%
Not applicable	57	7.0%
Total	**819**	**100.0%**

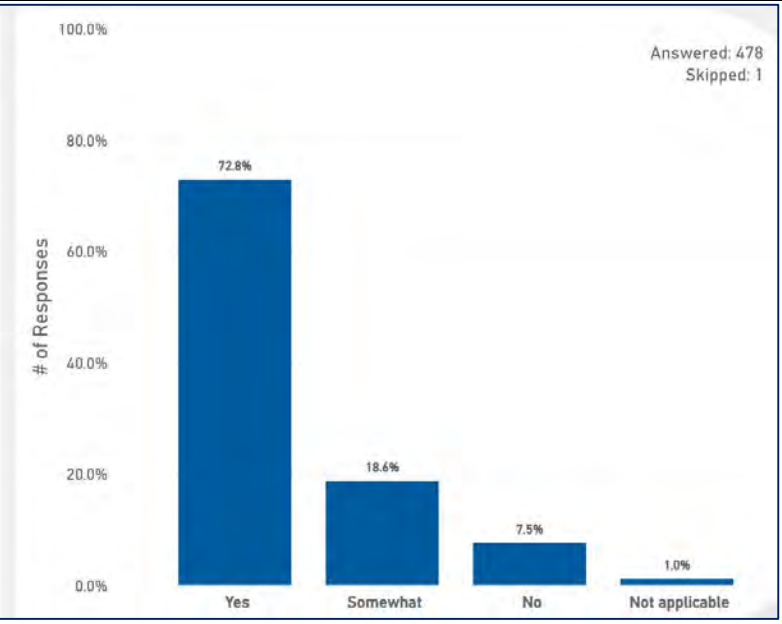
All Responses



58. Have you felt burned out from your work?

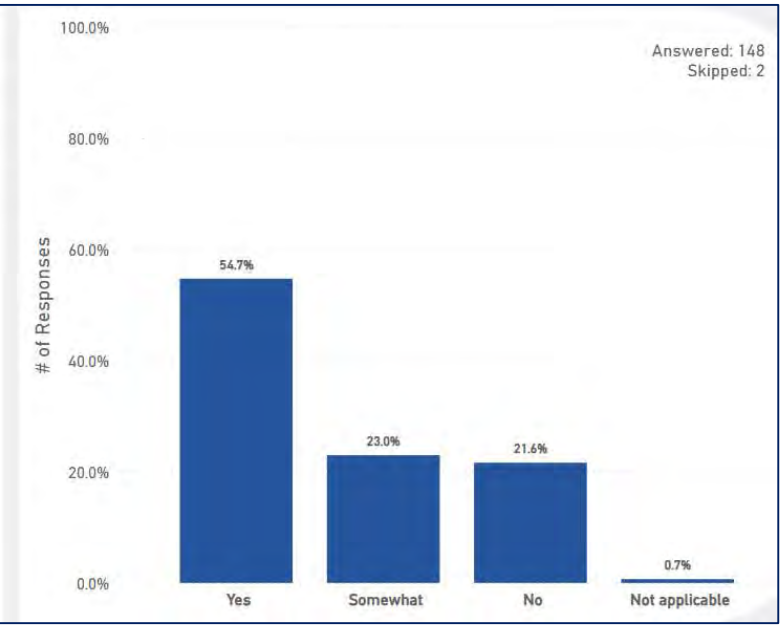
Survey Responses	# Responses	% Responses
Yes	348	72.8%
Somewhat	89	18.6%
No	36	7.5%
Not applicable	5	1.0%
Total	**478**	**100.0%**

Retail Chain Pharmacist



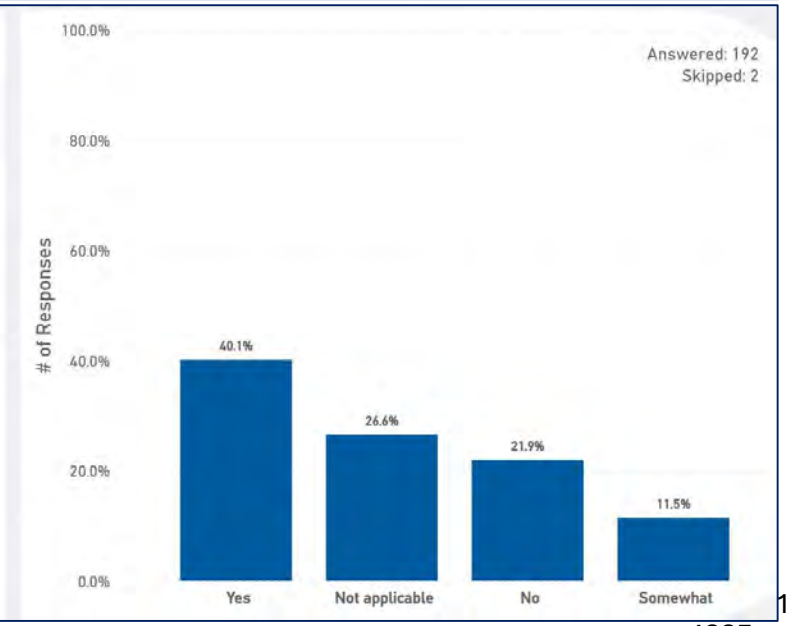
Survey Responses	# Responses	% Responses
Yes	81	54.7%
Somewhat	34	23.0%
No	32	21.6%
Not applicable	1	0.7%
Total	**148**	**100.0%**

Institutional/Hospital Pharmacist



Survey Responses	# Responses	% Responses
Yes	77	40.1%
Not applicable	51	26.6%
No	42	21.9%
Somewhat	22	11.5%
Total	**192**	**100.0%**

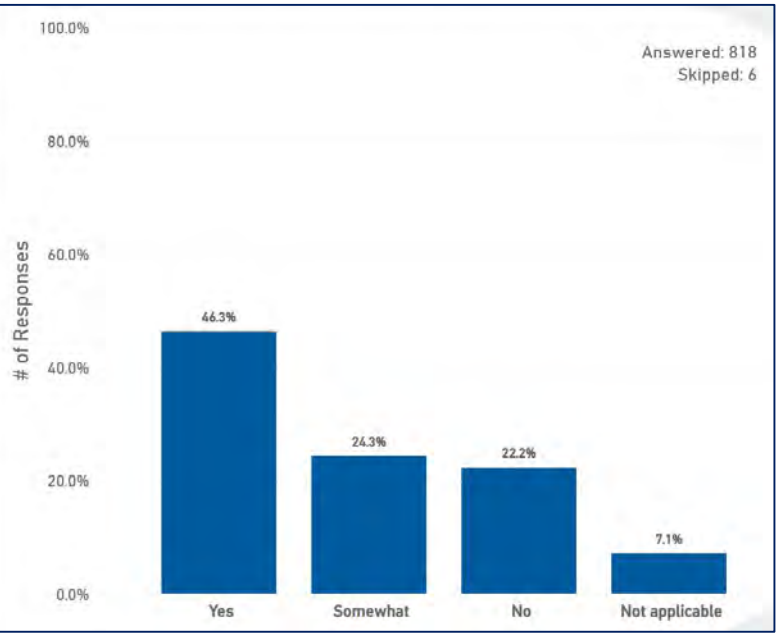
Other



59. Does your job often negatively affect your mental or physical health?

Survey Responses	# Responses	% Responses
Yes	379	46.3%
Somewhat	199	24.3%
No	182	22.2%
Not applicable	58	7.1%
Total	**818**	**100.0%**

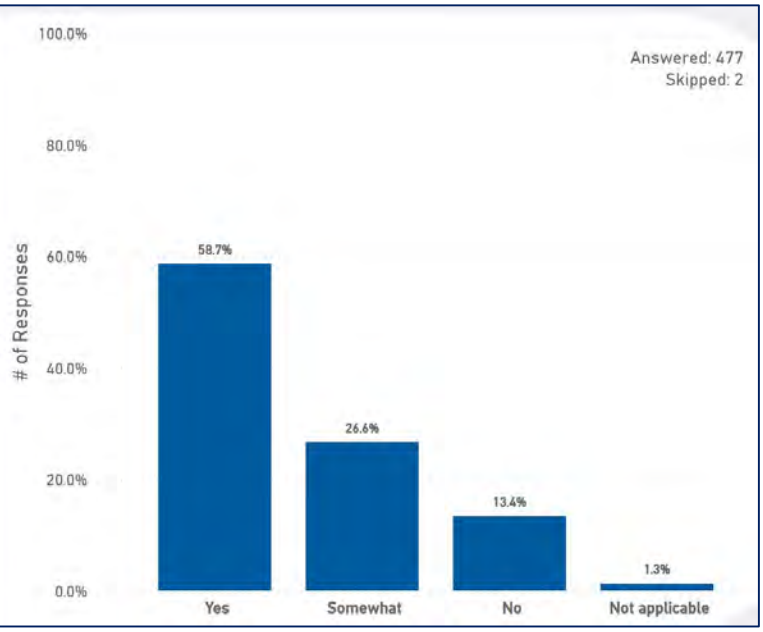
All Responses



59. Does your job often negatively affect your mental or physical health?

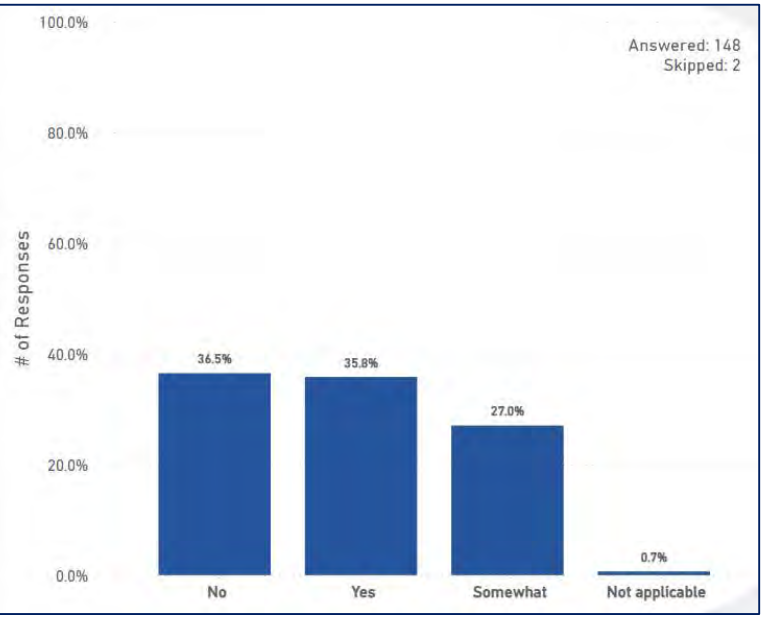
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	280	58.7%
Somewhat	127	26.6%
No	64	13.4%
Not applicable	6	1.3%
Total	**477**	**100.0%**



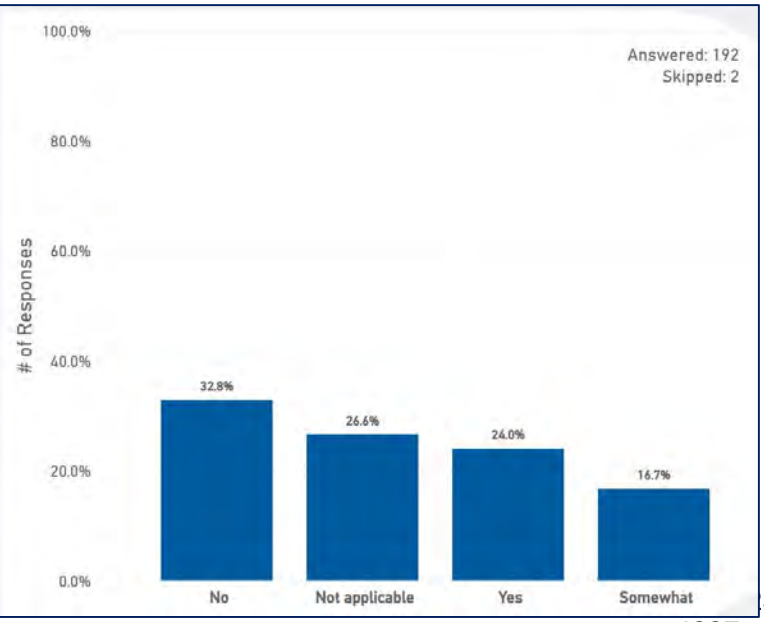
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
No	54	36.5%
Yes	53	35.8%
Somewhat	40	27.0%
Not applicable	1	0.7%
Total	**148**	**100.0%**



Other

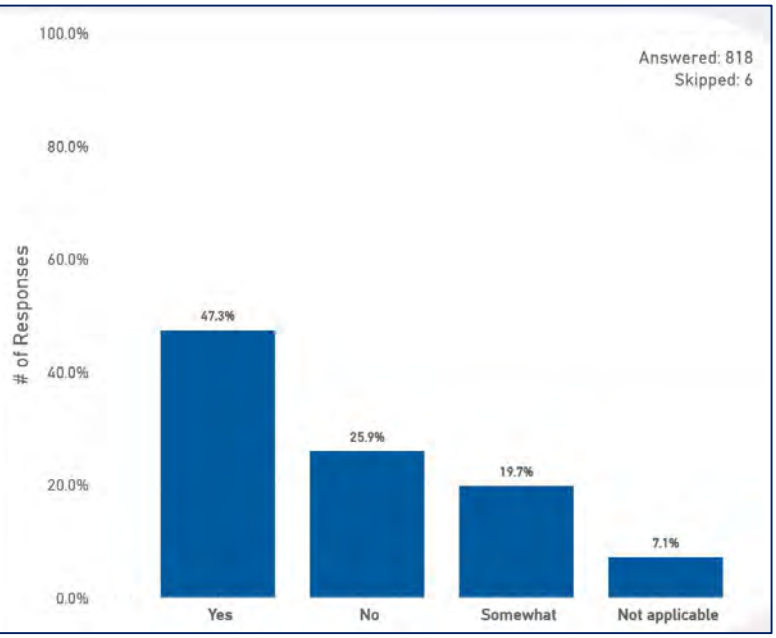
Survey Responses	# Responses	% Responses
No	63	32.8%
Not applicable	51	26.6%
Yes	46	24.0%
Somewhat	32	16.7%
Total	**192**	**100.0%**



60. Have you often been bothered by feeling down, anxious, irritable, depressed, or hopeless because of work?

Survey Responses	# Responses	% Responses
Yes	387	47.3%
No	212	25.9%
Somewhat	161	19.7%
Not applicable	58	7.1%
Total	**818**	**100.0%**

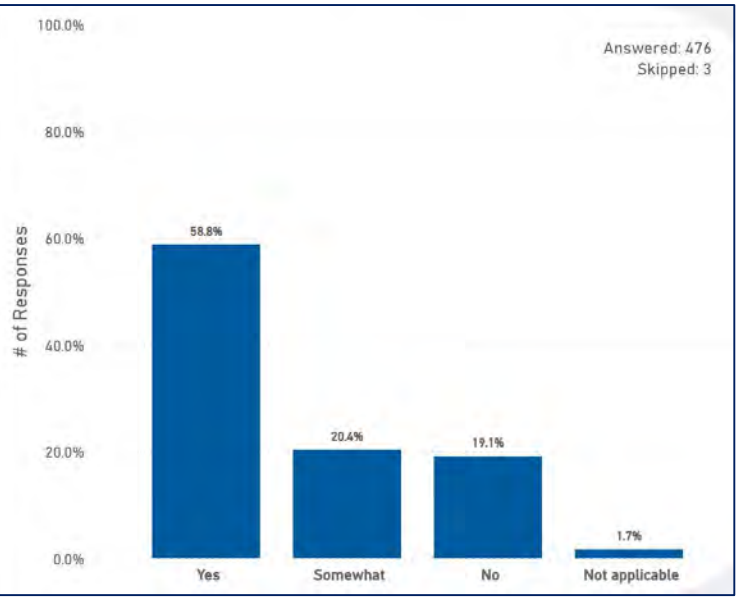
All Responses



60. Have you often been bothered by feeling down, anxious, irritable, depressed, or hopeless because of work?

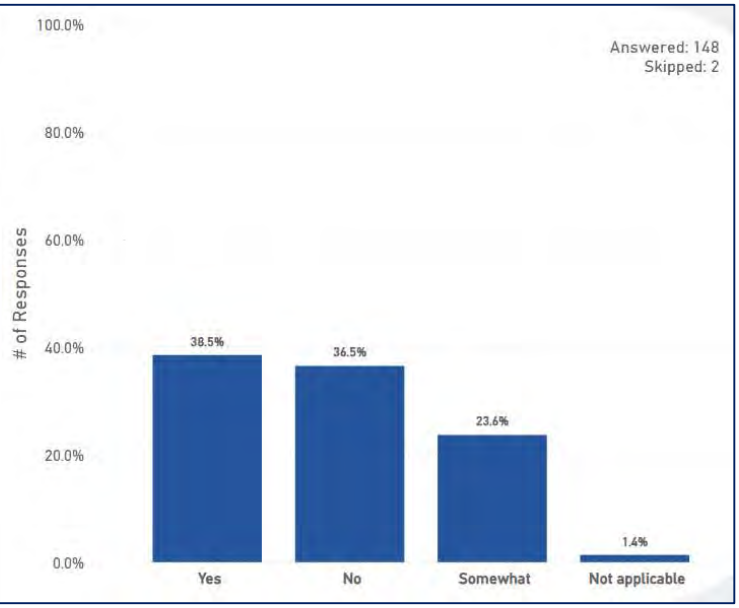
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	280	58.8%
Somewhat	97	20.4%
No	91	19.1%
Not applicable	8	1.7%
Total	**476**	**100.0%**



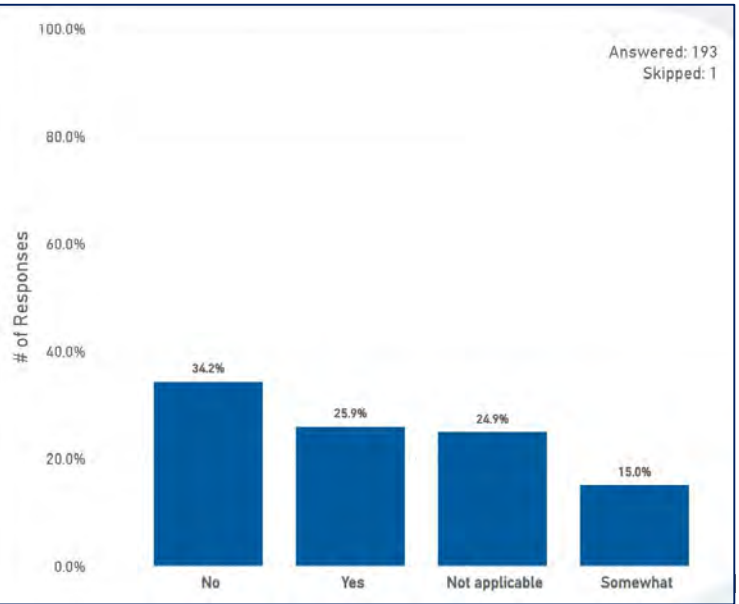
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
Yes	57	38.5%
No	54	36.5%
Somewhat	35	23.6%
Not applicable	2	1.4%
Total	**148**	**100.0%**



Other

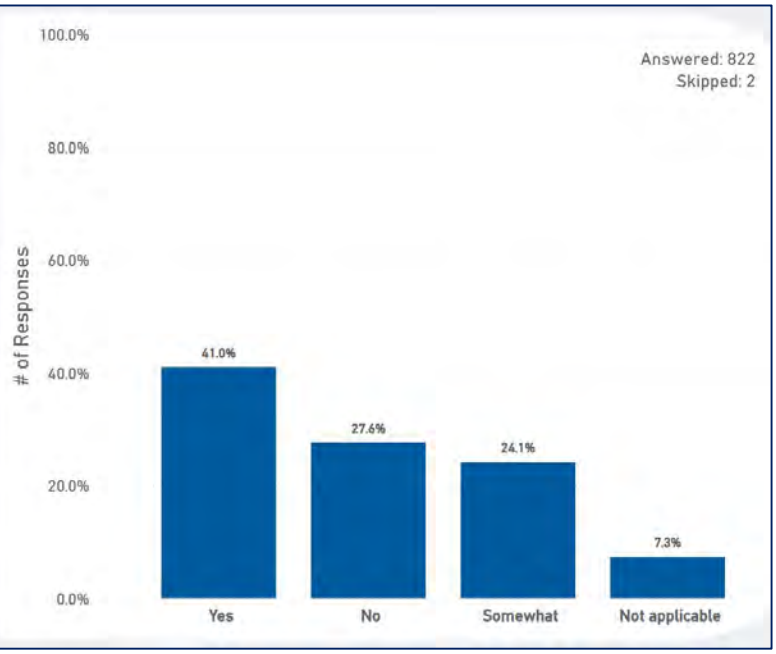
Survey Responses	# Responses	% Responses
No	66	34.2%
Yes	50	25.9%
Not applicable	48	24.9%
Somewhat	29	15.0%
Total	**193**	**100.0%**



61. Have you felt all things you had to do at work were piling up so high you could not overcome them?

Survey Responses	# Responses	% Responses
Yes	337	41.0%
No	227	27.6%
Somewhat	198	24.1%
Not applicable	60	7.3%
Total	**822**	**100.0%**

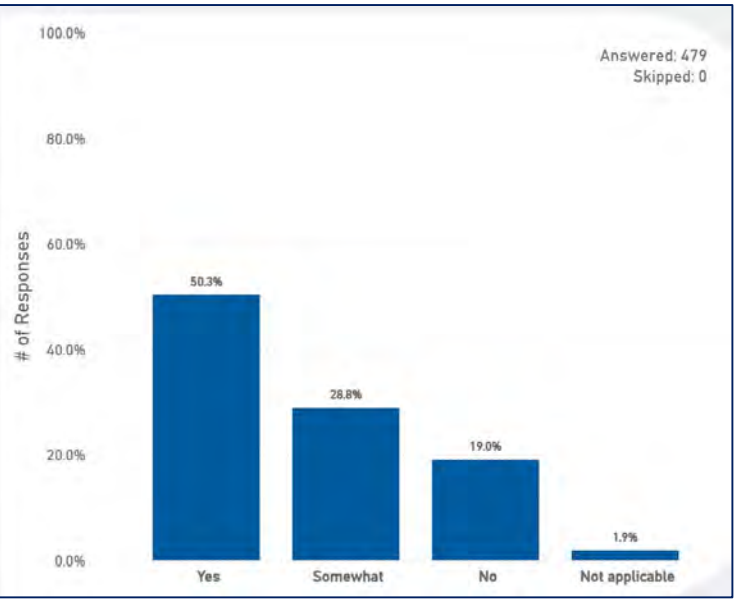
All Responses



61. Have you felt all things you had to do at work were piling up so high you could not overcome them?

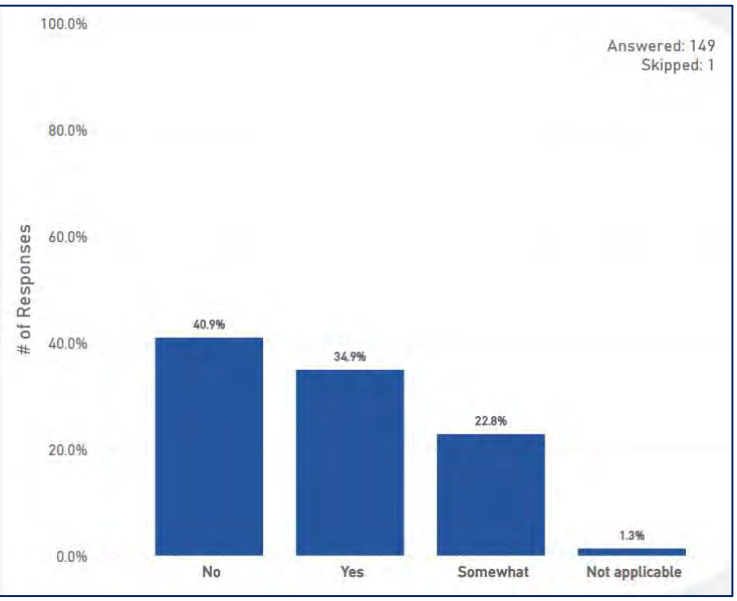
Retail Chain Pharmacist

Survey Responses	# Responses	% Responses
Yes	241	50.3%
Somewhat	138	28.8%
No	91	19.0%
Not applicable	9	1.9%
Total	**479**	**100.0%**



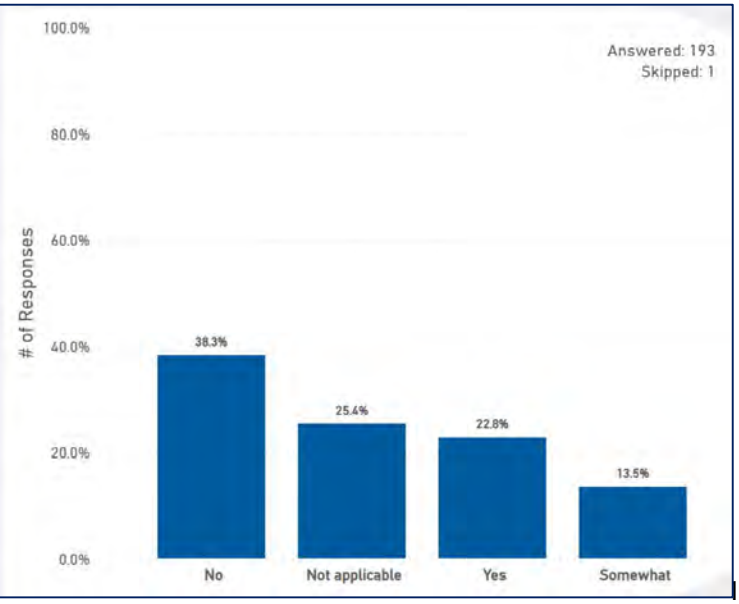
Institutional/Hospital Pharmacist

Survey Responses	# Responses	% Responses
No	61	40.9%
Yes	52	34.9%
Somewhat	34	22.8%
Not applicable	2	1.3%
Total	**149**	**100.0%**



Other

Survey Responses	# Responses	% Responses
No	74	38.3%
Not applicable	49	25.4%
Yes	44	22.8%
Somewhat	26	13.5%
Total	**193**	**100.0%**



	A
1	**Question 55: What workplace conditions, if any, do you believe should be addressed at your primary practice setting to promote patient safety? What suggestions do you have for improving the condition?**
2	**Question 3: Which of the following most closely describes your primary practice setting? b. Retail Chain Pharmacy**
3	**Responses**
4	1) increase rph and tech help. 2) move testing and vaccinations out of the pharmacy to it's own mini clinic.
5	1. Eliminate workload metrics (hours of tech help are being based on script counts/sales). Our community is primarily retired seniors and the volume/quality of patient care is more demanding/time consuming. Since the pandemic, Vons has "CUT" 10 hours of pharmacist on duty/week....leaving us very short staffed to upkeep the volume and demands which has increased tremendously with overwhelming vaccines, scripts, phone calls. Our location demands for more patient care, more questions, more EVERYTHING and with the cut of pharmacist hours, the entire staff is overwhelmed feeling defeated on the daily. 2. Our layout of the pharmacy is not safe for staff nor does it allow the pharmacy dept to safely and efficiently perform pharmacy tasks. The front counter is jumpable at 3 feet tall and wide open to encourage anyone to jump over at anytime. Majority of staff are females who works the night shift and we do not feel safe. Along with the wide open layout, the pharmacist and techs are widely displayed to welcome "all customers in sight" to stop and interrupt the staff in the middle of processing/dispensing prescriptions to ask where things (bread, cheese, soda, napkins, etc) are in the grocery store and being majority of clients elderly...you have to stop and go escort them to the item in the store. And this is a constant disruption in the pharmacy staff performing pharmacy tasks. Safety concerns of the floor plan has been voiced multiple times with State Board but still no result.
6	1:1 ratio of pharmacist:tech should be the LAW for safety so big companies cannot use shrinking of hours to minimize technician help for to forgo safety and maximize workload for profit
7	13 hours shifts Waived lunch breaks, no time to take breaks and not falling behind work load
8	A legal minimum of pharmacist to technician ratio based on the # of Rx filled on average for that day of the week. Techs in training do not count.
9	Add more technicians
10	Add pharmacist
11	Adding an additional Pharmacy Technician in order for me to not feel rushed in the verification of each prescription and medication dispensed.
12	Addition of staff and elimination of distractions would greatly improve patient safety. A closed room or section in the pharmacy for pharmacists especially in retail would be helpful in decreasing interruptions. A maximum limit of prescriptions processed by a pharmacist in a day would also be beneficial to decrease the pressure in filling prescriptions without further checking their efficacy and safety for the patients' therapies. Business metrics should not pressure pharmacists. Chairs for staff in retail pharmacies can also be helpful in reducing fatigue. There should be assigned staff separately for dispensing and non-dispensing services for the day.
13	Adequate experience technicians
14	Adequate pharmacy staff (cashiers,Pharmacy techs to take care inside store and DRIVE THROUGH Patients. There should be a day set for immunization and a pharmacist to do Immunization so that the verifying pharmacist can concentrate.
15	Allowing more pharmacist overlap
16	Allowing more time to address mild to moderate drug interactions when counseling
17	As a PIC at my current employer we are required to work 9.5 hours per day 5 days per week. This is a long day/week of high pace work and forceful concentration to not make any mistakes. There should be a limit to how many hours a day or how many hours per week a salaried pharmacist can work, 40 MAX! Either four 10 hour shifts or five 8 hour shifts, even as salaried. The employer mandates PIC work 45 hours per week - which is a safety concern in my opinion. By the end of the day I'm finding myself making more errors, and especially by the end of the week.
18	As pharmacists in retail chain, we often find ourselves in a relentless cycle of multitasking and extended work hours due to the demanding nature of our work, which is exacerbated by a shortage of pharmacy technicians. This shortage compels us to undertake additional roles, including technician tasks, administering vaccinations, and handling non-patient related interruptions, all while ensuring patient safety. The pressure to meet efficiency metrics further intensifies this issue, making breaks seem impractical. Consequently, I often forego rest and meal periods, not explicitly required by my employer, but out of necessity to manage the workload. This situation impacts both our well-being and the quality of patient care, underscoring the need for a more balanced and sustainable work environment in pharmacies.
19	Assign extra help
20	At my particular retail pharmacy, we are extremely understaffed and cannot even begin to keep up with the workflow. Corporate only cares about how we can keep up with imposed metrics, patient safety is secondary to everything. Patient safety and concerns are only validated when they start to affect metrics or the bottom dollar.

	A
21	At my workplace there is not enough staff at certain times of the day to support the inflow of prescriptions that come in, answer the calls, ship medication, et . There should a standard minimum number of staff at all times of the day. My company does not allow for sufficient hours for all staff to maintain the pharmacy. Employee hours are held hostage by how well we perform towards metrics (i.e. number of vaccine given, calls to patients get more vaccines, etc).
22	Being able to focus on one task at a time would be the biggest safety improvement. Not sure how to make it happen but better staffing would be a great place to start.
23	Being able to focus without interruption.
24	Being consistently understaffed needs to be addressed by retail chain pharmacies. A legal statute that requires a minimum number of techs on during business hours depending on script volume would make sure the pharmacy is staffed.
25	Better phone systems to deter basic functions that can be done electronically.
26	Better workflow with each patient's meds being grouped together. Little interruptions and distractions. The phone calls are out of control since it rings a lot and not enough bodies to be at many stations from register to drop off to fill and answering the 4 or 5 lines that constantly rings. We in the pharmacy world are burdened by metrics and workload and the lack of breaks. Somedays I work 7am to 8pm and w/o one single break. Prescriptions are lined up everywhere and it's easy to mix up meds among patients. Corporations want more money each yr to satisfy growth and PBM want to pay out less so easiest way for corp to grow each yr is to cut cut cut labor hours. It's sad and I wish I had gone into dentistry instead when I went to college for pharmacy. I am happy to hear enrollments are down and hopefully enrollment will decrease even more.
27	Bottom line is more pharmacist/technician help. or limit number of prescription for pharmacist to verify per 8 hour shift
28	Cap on the number of prescriptions a pharmacy can fill. Cap on the number of calls that can come in. Hundreds of calls come in
29	central phone system-off site phone employees
30	clerk help and phones not ringing every 6 seconds and mgmnt getting upset cause you cannot answer all the phone calls! better phone system easier to use
31	Coaching
32	Companies should not continue to pile up more and more duties on pharmacists and the techs without providing extra help, especially when it comes to higher volume stores. There is already enough work to be done filling 1000+ scripts daily, administering shots, counseling patients, giving OTC recommendations, and then there are more tasks being given as if there is not already enough work to do. The extra tasks are being given or added to a day without extra help. There should be more pharmacists to help, especially at busier stores. Having more technicians will help, but that also gets more stress on the pharmacist having to watch over 3 techs plus the cashiers.
33	Constant interruptions of Pharmacist only tasks along with unreasonable mandatory metric goals
34	constantly adding additional metrics and tasks. excessive pressuring to reach goals. Pushing for excessive amount of vaccines and comparing other stores. Constantly made to feel we are under performing even when doing more than last year with less help. It takes a toll on everyones mental health. Its about profits but pharmacists pay increases are not keeping up with inflation. Does not make any sense these days to take on 225k in student loans and spend 8 years going to school. Return on investment is better becoming a technician with no school, no loans. Techs might get a raise of 5-10%. Pharmacist are lucky to ever see 1%, and that is over a few years.
35	Consultations are not conducted confidently and effectively due to time constraints. A separate window or area should be made available for private consultations.
36	Continue to promote the use a of technology that is being developed and the Board should be more proactive to amend regulations to broadly allow the use of these technologies
37	Corporate and district managers should stop threatening pharmacists to fill all c2 medications without speaking to the prescriber about the patient's pain management therapy plan especially if it is their first time and they are starting off with a 30 day supply. Patient safety is important but corporate tells us not to delay therapy by talking to the prescriber first.
38	Decrease phone calls and patient traffic in the pharmacy so the pharmacy has more uninterrupted time to finish task in a timely and safe manner.
39	Decrease the required paperwork and excessive processing we have to do for all control prescriptions
40	Decrease workload for pharmacists, increase ratio of tech:pharmacist, decrease the interruption while pharmacist is verifying the prescriptions, no vaccination (we are pharmacy, not immunization clinic), increase tech hour (they cut hour so sometime pharmacist has to be alone in the pharmacy or just have 1 tech for 2 hours, or all day)
41	Decreasing or eliminating pharmacist interruptions, decreasing or eliminating the amount of non-dispensing responsibilities pharmacists have.
42	Designate 1 to 2 hours a day where we only do vaccines and then no other vaccines can be administered after that time window.
43	Do not have enough technician help, meeting metrics and provide non-dispensing work are greatly affecting patient safety. If corporation could eliminate metrics including flu shot goal that would help pharmacists have more time to focus on patient safety.

	A
44	Do the math it is simple. There is only one question to be asked and answered all of the previous questions were of no consequence. The only question is how long does it take to safely fill one prescription from data entry to final verification?Do the math genius.
45	Doing or testing that shouldn't be pharmacist like point of care and test to treat for flu , covid and strep throat testing
46	Don't give us the CVS corporate answer. Be honest that there is a problem by acknowledging it. Then fix the issue as opposed to sugar coating the issue with positivity. Workplace conditions that needs addressing are hour cuts, lack of help, & metrics quo
47	Due away with metrics and non-dispensing tasks. Without metrics being used to evaluation my performance, which affects paid rate and raises, I will be able to focus on patient safety and not have to worry about non-patient related tasks or concerns.
48	Eliminatating the need for the pharmacist to be the main person answering calls while doing so many other tasks, constant interruptions by working alone for 3-5 hours while answering every question, consultation, and maintaining workload plus metrics, having 2 or more pharmacists per shift to alleviate the stress and workload .
49	Eliminate all metrics.
50	Eliminate metrics
51	Eliminate mtm tasks, have a mid pharmacist with the volume we fill.
52	Eliminate non dispensing responsibilities for pharmacists and metrics.
53	eliminate phone calls and phone metrics, all phone related items.
54	Eliminate the practice of staffing the pharmacy with 1 pharmacist for a 12 hour shift. Provide adequate staffing (whether pharmacist or technician) to allow staff to take a break/meal period without totally overwhelming remaining staff. Eliminate the
55	Eliminate vaccine targets Script targets Rph overlap More tech hours
56	Eliminating COVID testing, strep testing and flu testing. These tests take up to 45 minutes to an hour
57	Eliminating high metric expectations regarding immunizations, as it creates many disturbances in workflow and encourages mistakes due to limited space within pharmacy; especially at peak hours.
58	Eliminating metrics and increasing pharmacy tech hours
59	Eliminating non-dispensing pharmacy related work
60	eliminating timing of checking and reviewing rxs
61	Eliminating workload metrics
62	Employee Burn out. Need. More techs
63	enough pharmacist and technician staffing
64	enough staff
65	Enough staffs
66	Even though the tech to pharmacist ratio is set by the State Board of Pharmacy, we get around it by saying the techs who are ringing out prescriptions are cashiers, thereby being in compliance with state regulations. The truth is they are techs.
67	Extra help
68	Faster response time with providers
69	For non-dispensing services should be scheduled on weekends ehen an extra pharmacist can give the said services so complete focus and attention can be given to appropriate services
70	Get rid of metric, increase number of pharmacist
71	Get rid of twelve hour shifts. Increase pharmacist hours. Allow for better pharmacist overlap of shifts to make calls, perform daily tasks and counsel patients.
72	Get supervision out of the practice of Pharmacy
73	Getting extra staff for Managing incoming phone calls..managing patients problems..
74	Give extra time to complete the requirements and training for for additional tasks that have been added.
75	Give more time for pharmacist to review and communicate with MD and patient

	A
76	Give pharmacist more power less bosses less accountability from people that are making $ from the pharmacy . There are numerous people that have never worked in a pharmacy , don't know the law or what it takes to fill a rx safely and completely . Many of these corporate executives , district managers , store managers , and assistant managers all make $ and have financial motive to push a pharmacist to fill a rx faster , give more vaccines , do more MTM's , sell more OTC's , get all your paper work done faster and many other duties that are irrelevant to the practice of filling actual rx's . All on the back of the pharmacist license . Why I ask ? What have not all but most of these people done to profit from me going through 6 yrs of pharmacy school ,busting my backside , coming in early ,staying late , and working in a very high stressed environment . At the very least NVBOP should make it law that Pharmacist clock in and out and get overtime pay for anything over 8 hrs/day and 40hrs/week . Salary should be done away with . 30 min for lunch is a joke . Every pharmacist should get a full hr lunch by law plus a 15 min break in AM and eve . No supervisor ,district manager or store manager should have any authority over a pharmacist if they are not licensed and approved by the NVBOP . With that the NVBOP should develop a set of rules and standards said supervisors have to follow. If someone is in charge of a pharmacist they are essentially in control of work load , quotas, and how much a pharmacist is pushed to meet financial goals . As it stands now pharmacist have to meet unreasonable goals or get reprimanded , bonus with held and or terminated . I know nothing will probably get done because this survey is probably just fluff for someone that wants to look good for there supervisor . Again someone thats making $ off of pharmacists . Very ironic .
77	Giving consideration to give enough time to focus and fill prescription
78	Have additional pharmacist working to share the workload of counseling, therefore limiting the times of being interrupted while verifying medication¨s and data verification
79	Have enough Rph and techs depending on how many scripts Pharmacy fills per day
80	Have more technicians trained for immunizations, especially during flu season.
81	Have non-pharmacy staff prohibited from assigning any tasks to PT , PTT and cashiers; also be prohibited to tell Pharmacist to change focus or priorities.
82	Have not worked in a pharmacy for over 10 years.
83	Having additonal help, prohibition of metrics/quotas, pharmacists shouldn't be required perform non dispensing duties that allow the retailer's bank account to grow exponentially without any regard for patient safety.
84	Having more technician hours, our pharmacist shouldn't be working alone at any one time during the day. Law should require a minimum amount of man hours based off of prescriptions filled to help prevent retail pharmacies from creating understaffed condit
85	Having more technicians and giving the PIC enough technician hours to be able to schedule them.
86	Having more technicians or another pharmacist to help process and fill prescriptions and answer phone calls would allow the verifying pharmacist to have more time and not feel œrushed when verifying prescriptions.
87	Having more than 1 pharmacist scheduled during weekdays .
88	Having one pharmacist doing non dispensing duties for a designated amount of time (ex: 10a-3p). Also having patients make appointment to this designated non dispensing clinic time and not accepting walk-ins. There's distractions as soon as someone walks up and requests this shot or that shot.
89	Having sufficient tech hours so that a pharmacist should NOT have to open or close or work any of their shift without at least 2 technician
90	Having the freedom to discharge patients who are abusive to pharmacy staff.
91	hire pharmacists to take care of the mtm tasks and other non-dispensing related services, such as vaccinations, point-of-care testing, chronic disease management, collaborative practice agreements, staff education or quality improvement projects
92	Hours should be based on a yearly calendar. We should be able to utilize hours that are unused from one week to another and hours should be based on productivity. Meaning you should get more hours with newer staff as they cannot prefer at the same level as experienced technicians.
93	How many technicians are allowed per pharmacist.
94	I am answering survey questions based on my experience in retail pharmacy. I am currently at a remote hospital pharmacy where our only need is more pharmacists and uninterrupted breaks. In retail. Testing services should be completely separate from vaccination services (not the same building). Testing should not be allowed to be done through the drive-thru. Testing should be outside or have a separate entrance from all other patients and have a separate staff for all these procedures with appropriate sizes of all PPE necessary.
95	I believe my employer should place the responsibility of their flu/vaccination models on someone else for flu seasons, or it needs to be wildly decreased. For the month of October, we were expected to do up to 150 vaccines per day on top of meeting pharmacy demands
96	I believe patient care calls and prescriber follow-up calls are an over burdensome metric. In my practice setting, we communicate with patients via automated phone calls and text messages. There is redundancy all ready built into the system. We communica

	A
97	I believe that the addition of technician hours would be most beneficial to my practice. Starting this year, the budget was significantly cut, leaving the pharmacist alone most of the time the pharmacy was open.
98	I believe there should be a 1:1 ratio of pharmacist:technician at all times. A lot of times as a pharmacist, I am working alone for 6 out of the 10 hours I am there. It is hard to promote patient safety when I'm being pulled to do 6 different things duri
99	I do not want or think it is a good idea to have patients come into retail stores for disease testing.
100	I feel like most stresses are coming from corporate pushing for us to meet certain goals (metrics) ei, increasing our script count, vaccine goals, Clinical numbers, autorefill, 90 days fills, Medication Therapy Management. I spend most days worrying about meeting metrics rather than focusing what I went to pharmacy school for, taking care of patients, drug interactions and accuracy. Hopefully the board can step in and do something about this issue.
101	I feel that it is important to take breaks and we are not able to do that. My store is busier now than when I first took over the store. Before the pandemic we use to have 3 pharmacist scheduled Monday through Friday, now that I am busier because we even
102	I need one pharmacist just for consulting with all the medications we are expected to consult on, then another pharmacist just for vaccines and phone calls, and then a third pharmacist just for verifying and product review of medications. Sure, technicians can vaccinate but they do not want to without being incentivized as they feel they do not get paid enough for the risks that come with being a vaccinator. I think it should be a requirement for companies to have a cleaning service to clean the pharmacy. There is not enough time in the day for pharmacists and/or technicians to clean and it is also not our job. We are a health care environment that should have a cleanliness standard. My pharmacy has reeked of sewage for months. This smell is so bad that we wear masks and are getting headaches. I have put in ticket after ticket with our fix it center. Plumbers have come by to check on it with no help. Finally someone came to smoke out the pipes to see if there was a leak and the whole pharmacy became so smoky that the staff members could not breathe. Higher up members were upset when the floating pharmacist shut down the pharmacy while the smoke was in there. These conditions are not workable sometimes. I do not know any patient that would want their medications that they ingest to come from a pharmacy that reeks of sewage and has smoke everywhere.
103	I think every chain should have a call center about pt counseling over the phone
104	I think the company that I work at is great and it gives us a huge support.
105	I was a pharmacy manager for 14 years. At first I would have three technicians scheduled throughout the day. Around 2015, I was down to being able to only schedule one pharmacy technician every day and I was doing more prescriptions and more non-dispensing tasks. I feel that I am a very good pharmacist that can multi-task. With one technician, there is no way that I can handle the in-window, out-window, phones, typing prescriptions, filling prescriptions, checking them, and doing vaccinations. I simply can't be in each spot at the same time. When you have a line of patients staring at you and the phone ringing, your stress level goes way up and mistakes are made. I had to quit and move to another pharmacy setting, even though I feel that community pharmacy is my calling. Towards the end of my time as a community pharmacist I started to have panic attacks while driving to the pharmacy. I knew that I would not have enough help and that I would be under stress all day. (Don't forget, I was trying to do all of these things by myself before and after the technicians shift or when they were on break and lunch. Also, the technicians called out a lot because the way that they were treated by the company.) Patient safety was clearly affected by the lack of concern by the company.
106	If additional responsibilities are given to the pharmacists extra overlap and technician help should be given right away not told it will get adjusted in a few months automatically by the system
107	If our PIC/Rxmanager would stop being rude and disrespectful to our patients.
108	If we are going to be expected to be clinicians with our patients and counseling is being required, then an adequate amount of time needs to be given to actually review patient's info, contact doctor's, review guidelines, etc. We should not be held resp
109	If we became hourly then we'd be entitled to our breaks and 30 min lunches right now technicans are allowed but for us no one cares but it doesn't make sense we need them more to catch mistakes , or make mandatory brakes after two hours even as salary, r
110	If we can have 4 techs/ 1 pharmacist ratio
111	illegally be asked by corporate to increase the number of vaccination and metrics, and have nonstop cut technicians hours.
112	Immunization technician on schedule all day to eliminate pharmacist doing all vaccinations 4 or more technicians on schedule or another pharmacist
113	Impossible to meet payroll standards. Front end store using rx payroll dollars and forcing rx to cut help. Minimum staffing requirements enforced by state.
114	Improve staffing levels and allow for proper training of technicians
115	Improve staffing, preferably a midshift pharmacist, and adding at least one more technician to the afternoon/night shift to allow prescriptions to get filled continuously throughout the day and not leave a large load on the following day.
116	Improved staffing will help with the work load. As well as reducing non-dispensing duties like numerous calls that should be replaced with electronic communication.

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117	Improved telephone answering system, more automation
118	Improvements to the computer system to help prevent errors
119	in our setting, at our current fill level, we need to have 2 techs (8 hr shifts) per day. I think a single tech on the weekend is sufficient at the fill levels we are at. currently we are at 1 tech per day and 1 pharmacist trying to fill 160 average per day, including all duties. fill, dispense, phone, shots, counseling ect. there is a real question about making so many split second decisions in the course of a day is did i make every one correctly? I sincerely hope so. however the stress on some days due to work load can be overwilling.
120	In the beginning, I would like to discuss the pressure from the pharmacy manager. There is pressure that will lead to better improvement, but there is pressure that will lead to an unsafe environment to work. This exactly happened at the retail pharmacy currently. The pharmacy manager demanded staff pharmacists verify the prescriptions at unusual and inappropriate times. Staff pharmacist had to verify and work faster than normal process, so the pharmacy manager could get the payment bonus from the corporation. This leads to extreme events that can cause medication errors and an unsafe environment to work. The pharmacy manager demanded staff pharmacists counsel prescriptions and give vaccinations as quick as possible in as few seconds. This is not the right way to practice pharmacy, pharmacy manager should understand the importance of the necessary steps to practice pharmacy. In the normal process, the pharmacist needs to take time to discuss with the patient the usage of the medication, side effects, the dosage, drug-drug interaction, allergies, the history of the vaccinations, and so on. The pharmacy manager forced the staff pharmacist to skip most of the steps and work as fast as possible. There is a very high risk for staff pharmacists to practice and work in this condition. Secondly, I would like to mention pharmacy manager did not know how to train a new technician or technician-in-training. As a new hire, technicians will need several months to practice and perform hands-on experience at the pharmacy. The pharmacy manager forced them to work faster and threatened to write them up for any mistakes at the pharmacy. This contributed greatly to the medication errors that can lead to serious events. As a result, I would like to recommend not putting pressure on the new staff and letting them have enough time to practice and get used to the environment. In addition, the pharmacy manager did not know how to divide tasks between the staff. The staff pharmacist had to take on more responsibilities than normal due to the new staff did not have enough train. As a result, the normal process of the pharmacist such as typing the prescriptions, pre-verification of the prescriptions, product dispensing, final verification, and even the insurance process. The staff pharmacist had to do all the steps instead of dividing the tasks among all the staff. This contributed to medication errors as well. Lastly, the pharmacy manager kept track of how many times the staff went to the restroom every day at work. I do not know why the pharmacy manager was doing it as her policy. This is an unusual policy compared to other retail chain pharmacies, and it leads to unexpected pressure on the mentality of all staff at the pharmacy.
121	Increase help in the pharmacy, i.e more staffing. Removal of metrics and non pharmacist related tasks.
122	Increase hours
123	Increase in pharmacist overlap/ hours. Increase in technician hours. Maybe Increase the tech ratio to 4 to 1 but nothing more than that. I believe more would lead to a bottle neck and errors.
124	Increase in technicians and cashiers hours all throughout the day. Not just mornings, but evenings as well
125	Increase in the pharmacist staffed. there should be an opening, mid, and closing pharmacist every day except the weekends to ensure adequate overlap to help ensure more patient safety and better clinical conversations between patient and pharmacist.
126	increase internet speed computer systems/programs, better organization for medication pick up
127	Increase number of pharmacists staffed, allow for budget to do so, bonuses or salary raises that are greater than the cost of living percentage increase
128	Increase number of pharmacy technicians
129	Increase number of technicians, proper training of technicians before engaging in working in the pharmacy, move some of the non prescription dispensing activities to call centers.
130	Increase of immunizing pharmacy technicians.
131	Increase pharmachy technician and add a midshift pharmacist. The other day we did over 800 prescriptions with four technicians and two pharmacist with no overlapping schedule. In addition, we are required to do patient calls for mtms, adherence calls, de
132	Increase pharmacist staffing or overlapping shifts.
133	Increase Pharmacist staffing. CVS Walgreens Walmart need to be accountable
134	Increase staff
135	increase tech help. solve the problem of patients using good rx because their prices dont match pharmacy prices. It disrupts flow and increases chances of mistakes
136	Increase tech ratio. This will support rph in being able to reduce distractions, provide best patient care and practice at the top of your license while still providing essential services for the community.
137	Increase technician and pharmacist hours so that no one has to overwork and get burnt out.

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138	INCREASE TECHNICIAN HOURS, PAY THEM A FAIR WAGE, AND STOP INTENTIONALLY AND REGULARLY USING SALARIED PHARMACISTS TO WORK OVER BASE HOURS TO KEEP YOUR PROFITS HIGH.
139	Increase the number of techs who vaccinate. Pay techs more for vaccinating.
140	Increase work hours allocated to the week. Pharmacist, PT and PTT increased. You can have all the PT's in the country, but if you are short on staffing hours you're allowed, makes no difference.
141	Increased amount of technician help, Immunization clinics without designated immunizer should not be allowed
142	Increased pharmacist hours would help to alleviate the interruptions for the dispensing pharmacist.
143	Increased staff across the board to manage point of care services and prescription work load. Technician pay increased to increase retention and quality of work.
144	Increased staffing and directing non-dispensing and non-patient responsibilities away from pharmacists to improve patient safety. Suggest scheduling more shifts or more staff to focus on non-dispensing and non-patient responsibilities.
145	Increased staffing is a must. At the retail pharmacy we need time to call doctors to address interactions and the opioid epidemic. Instead we are making call after call to patients who have already expressed they don't want to be called for pharmacy programs such as MTM or Save a Trip refill. Metrics such as verified by promise time is insane. Time and time again I find myself taking short cuts in order to get the prescriptions done in time rather than prioritizing doing it safely.
146	Increasing pharmacist staffing would reduce interruption during verifying process that would promote patient safety.
147	Increasing ratio of technicians to pharmacists. Decreasing the non dispensing tasks that the dispensing pharmacist should do during the shift
148	Increasing Technician help to schedule every service offered at the pharmacy and manage waiting times accordingly. That will free the pharmacist to focus in patient care.
149	Increasing the pharmacy technicians allowed to work. Currently have 1 technician (maybe 2 if there's one overlap day) and they want us to cut an hour from each of them so the pharmacist is alone for an hour. I'm currently typing RX, verifying, filling co
150	Increasing the tech to rph ratio would be extremely helpful in assisting with removing tasks that technicians can do from the rphs
151	Interruptions by customers wanting to know the location of a product or to check out.
152	Interruptions coupled with excessive workload with added services required to be provided by pharmacists along with supervising technicians who are providing pt. care has dramatically increased the risk for medication errors. Chains insist they have SOPs and technology in place to alleviate the strain of the workload and ensure pt. safety however, they and the Board are well aware that IF these SOPs are followed, there are not enough hours in the day to dispense meds within the time they want with the pharmacist staffing provided. The management pressures the staff into complying with the imposed metrics (which increase year over year with a corresponding need to 'cut hours') with various penalties for non-compliance. Yet they will not hesitate to implicate the pharmacist before a Board hearing as being at fault and 'If they'd only followed our SOPs this wouldn't have happened'. This is true of ALL chains. With that said, pharmacist staffing must be addressed long before any contemplation of increasing the tech/pharmacist ratio as pharmacists are the rate limiting step in this process.
153	It would be great if we had pharmacies with a front of the house and back of the house design. The front of the house could handle interruptions, counseling and questions. The back of the house would just concentrate on verification, dispensing, etc
154	larger pharmacy with today's needs in mind
155	Less emphasis on non-dispensing responsibilities and increase emphasis on dispensing, counseling, and patient care with relation to medication accuracy, ADRs, safety and efficacy. (Which also happens to be what we went to school for).
156	Less focus on metrics
157	Less focus on vaccinations and other ancillary services. They make all the money now since the PBMs take all our profit, but it still doesn't make it right that we need to do them on top of actual pharmacy work. My primary concern is filling prescription
158	Less interruptions and with enough time to finish my IV infusions before I go back to benching
159	Less interruptions while processing prescriptions, less non- dispensing duties (manager likes to delegate her responsibilities to us without taking us out of the work flow to complete them, or not coming forward to take care an angry or difficult patient
160	Less interruptions with vaccines, fixing drug shortages, more staff to answer phone calls or having a call center. Well trained pharmacists, consistent scheduling to lessen burnout.
161	Less interruptions, better technology to help on prescription errors and more staff.
162	Less interruptions. Pharmacists are responsible for everything going on in and around the pharmacy area and keeping an eye out so people don't jump the counter or cut in line or pick fights with other people in line while working on filling prescriptions
163	Less restrictions on payroll.

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164	Lessen non prescription filling activities
165	Locked cases getting constant interruption by public about open locked cases
166	Longer lunch break. We usually work 11 hours a day with only 30 minutes lunch. Sometimes patients do show up 1 minute before lunchtime to pick up their medications. In that case we only have 25 minutes left to eat our lunch. That's not enough time.
167	Lunch breaks. Albertsons pharmacy refuses to allow me a lunch break on a 12 hour shift.
168	Mainly just enough staffing and extra pharmacist. Counseling requires time and with just 1 pharmacist, it's hard to not fall back on time.
169	Mainly to have adequate staffing. I believe if a pharmacy is filling over 300 RX's a day it should be mandatory to have to staff another RPH for at least an 8 hour shift.
170	Mandatory brakes for pharmacists . Additional manpower just to answer the phone calls .
171	Mandatory staffing requirements for cashiers in a retail setting and separation of non-dispensing activities from dispensing activities (additional pharmacist staffing specifically for the purpose of completing non-dispensing activities)
172	Metric pushing despite false claims that they are not monitored and stymieing promotion of œextra services to gain more profits and volume of patients that burdens safety due to numbers and workload
173	Metrics
174	Metrics are oppressive and staffing is too low
175	Metrics out of your control should be eliminated because prhs are evaluated on performance ot goal instead of focusing on safe prescription dispensing by continuous measurement for : 1) increased vaccines goals despite vaccine hesitancy after covid 2) increase in number of new patients to the pharmacy 3)number of patients that become rx filling patients that you converted after receiving immunization 4) MTM ratings determined by lost points from patients who do no answer the phone (avoiding spam calls), from patients that refuse to agree to a complete medication review and discuss their private medications from a pharmacist/pharmacy they have never used (cold calls), from not wanting to fill 90 days for adherence under insurance when they cannot afford or when the pharmacy's cash discount offers 30 days for free, from prescribers or patients who decline to add/change prescriptions based on disease state even despite having tried and failed therapy in the past . All of these metrics are used to evaluate performance and raise and are required to be completed within hours allotted to pharmacy in addition to administering vaccines and filling prescriptions
176	More bodies to take care of phones and patients picking up. The techs who fill and the pharmacists who verify should be the ones uninterrupted to focus on their tasks. Getting rid of metrics and timing how long it takes to complete a prescription order would also reduce stress levels and allow more focus on completing the order correctly.
177	More help
178	More help needed
179	More help, from pharmacists and techs. The high stress and low pay is not enough to convince anyone to work retail, and the best way to lower the stress is to have more employees. There should be mandated breaks for pharmacists (there is no period of time I can sit and eat a snack without a counsel or phone call needing me, my company does not let us close for lunch because we have one hour of shift overlap which could be avoided by increasing pharmacist hours) Even the locations that close for lunch do not have a break for the closing shift pharmacist that is still working 8 hours. My managing pharmacist and I are both stressed by the end of our shift and a small break could greatly reduce that and improve attentiveness.
180	More help,dedicated cashier,no metrics
181	More pharmacist help
182	More pharmacist overlap and more technicians
183	More pharmacist overlap, fewer interruptions, breaks, better training
184	More pharmacist overlap, less focus on metrics
185	More pharmacists
186	More pharmacists and pharmacy tech help, eliminate metrics.
187	More pharmacists and technicians
188	More pharmacists on duty to fulfill vital patient consultation function. All pharmacies must have a bilingual staffer on duty during all open hours.
189	More pharmacists to overlook technicians and interns. Better systems that help RPh with verification.
190	More RPH overlap
191	More staff, less focus on numbers more focus on patients
192	More staffing . And if we can actually take our break decency without worrying that we are behind and need to finish our food in a hurry to go back to work
193	More staffing both pharmacists and technicians
194	More staffing. Less daily non- dispensing responsibilities.

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195	More tech hours is a must! Or at least a minimum of 1 technician at all time while the pharmacy is open. On most days, in the middle of flu season, we are open for 10 hours and there's only 4 hours with a tech. The other 6 hrs, pharmacist is working alone due to tech hours cut by corporate.
196	More technicians so pharmacists can focus on pre-verifying and verifying prescriptions. The expectation that pharmacists should also be doing technician duties such as filling, insurance issues, and checking out patients at the register while also be able to do vaccines and MTM on top of our regular duties.
197	More techs
198	More techs trained to vaccinate. Offer monetary incentives for training
199	More than 1 pharmacist for at least most of the day because so many tasks are œpharmacist only and it is exhausting when all those go to solely you and lead to massive amounts of interruptions or frustrations without the ability to stop for a minute.
200	More than 1 pharmacist should be on duty when the prescription volume is higher than 400.
201	More than 1 pharmacist. Depending upon the diagram of the pharmacy, such as drive thru, counseling rooms, robotics etc, increase pharmacist overlap.
202	More training for technicians
203	My biggest concern currently is the volume of vaccinations we are performing. This is not year round but has greatly affected my practice from Sept to Dec. I highly recommend/encourage vaccinations but it is not feasible to do 60-100 vaccinations in one day, verify an average of 400 prescriptions, and all the other activities that are needed in a pharmacy when you are the ONLY pharmacist and immunizer. The proposed solution has been to allow technicians to immunize, which I am grateful for to an extent but it does not solve the problem as much as my employer would like to believe. Many of my technicians do not feel comfortable immunizing. They chose their professions for a reason and many of them did not expect to need to perform this task. My opinion is if my technician that day feels comfortable helping me, that is great but I will not pressure someone to do something they are not comfortable with. It is not good for the patient or my technician. For an example, if my technician is not comfortable giving a 5 year old a flu shot, it will result in me spending the next 10-15 min trying to calm the child down. This takes up a lot of time away from dispensing drugs and it all adds up. I wish we had another pharmacist/nurse that would purely do immunizations Sept to Dec.
204	My concern is Performance "meterics" and an insult to the profession. It creates the sense that one must work faster to move on to the next prescription to meet "expectations" from corporate. We have 15 seconds to perform data entry correctness (pt name,DOB, prescriber, Drug name and strength, Directions, qty, day supply and 5 seconds for clinical review which includes history review, drug directions and interactions. Considering some patients have 20+ medications one can consider that an absurd metric!
205	My current workplace, I am very happy with. My prior pharmacy, which was much busier, always felt like we needed more staffing to safely meet patient needs. I was not the PIC at my prior pharmacy and had no control over changing the situation.
206	N
207	N/A
208	Na
209	Need better pharmacist pay and technician pay due to inflation. Better staffing for hours and pay for overtime for pharmacy teams. Cut back on excess ready-fill prescriptions and eliminate more with corporate metric demands. Advocate for more supportive services and provide more technician support if there is a call-out. Provide better pharmacy training for new hires.
210	Need cashiers
211	Need extra tech Or even train clerks to handle constant line at the Rey or answer non stop phone
212	Need more technicians
213	Need to have more than 1 Rph on duty for a good portion of the day to meet duty to counsel requirements.
214	Need to schedule more technician to Help pharmacist to fulfill duty
215	None
216	NOT APPLICABLE; SMALL VOLUME PHARMACY
217	Not enough staff during flu season
218	Not having to do vaccines appointment every 10 minutes and also employer asking to add more vaccines or take walk in patients for immunizations
219	not interupted per phone call
220	Number of days a pharmacist can work in a row before having a day off..
221	Of course we would all benefit from more staffing, whether it be technicians or pharmacists. The pharmacoeconomics of retail pharmacy simply does not allow for the staffing levels that are needed to provide QUALITY patient care which will expand our prac
222	Of course, we need to have enough staffs for a busy store with high volume >300+

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223	On my opinion adding more Rphs and technicians would be beneficial. One Rph can't verify, fill, counsel, answer phone, doing immunization, calling patients if they have questions, doing exception counts and other added responsibilities all in just one s
224	On site test and treat services. We do not have appropriate pharmacist staffing available to do that and safely fill prescriptions for patients. We either need more staff or to do less non dispensing activities.
225	Only do prescriptions, eliminate vaccines and MTM to another location.
226	Our volume is increasing and our management is requiring that tech hours be cut. They are using a 15 year old of better labor grid which does not account for all the tasks we are required to do. Also if a tech calls out they office does not find us help. we are expected to work the pharmacy with one RPh and one tech which is completely UNSAFE and the patients cannot be taken care of in my eyes. Plus we have a great deal of failures of the computer system that burn our time. Some can even create errors that we have to address. I constantly ask for fixes but nothing ever gets done.
227	Overlapping hours for pharmacists to have adequate help from other pharmacists. More techs can help but at the end of the day they cannot verify prescriptions and they can make mistakes but not liable for them since pharmacists are still their supervisors. To promote patient safety we have to have pharmacists working and enough coverage for consultations, drug therapy checks, immunizations, calling doctor offices for changes, etc.
228	Periodic breaks for pharmacists where we can sit down and clear our minds. Uninterrupted meal breaks would be nice. More support for answering phone calls would be nice.
229	Pharmacist is too accessible leading to many interruptions
230	Pharmacist overalp
231	Pharmacist should be paid from the point of entry to the pharmacy to exit, including extra hours worked to create a smooth workflow. More pharmacist should be allocated based on rx processed per pharmacy. There is no incentive to work at a pharmacy that processes 600+ or 1000+ per day vs one that has 200 rx per day. Companies need to increase tech pay for better retention and quality candidates.
232	Pharmacist should have a place to work uninterrupted by the public. At my employment this is a constant problem. Non pharmacy questions interrupting my work. People asking where is the peanut butter, etc. The technician can obtain my attention when needed for counseling or a problem. (Not shoppers)
233	Pharmacist should never be in the pharmacy alone. For pharmacist safety and ensuring that there will not be an error bec the pharmacist will have to type the rx, fill the rx and verify everything. The pharmacist working on prescriptions received that day
234	Pharmacist should not be doing point of care testing on top of dispensing responsibility
235	Pharmacist should not have to work alone during operating hours
236	Pharmacist staffing - we regularly have only 1 pharmacist on duty per full day while filling 300+ (commonly close to 400 or more) prescriptions a day on top of non-prescription tasks while trying to man more stations than we have bodies for (ie. drop off, filling, pick up, drive-thru, and pharmacist queues, someone out giving immunizations, etc). Our own metric system for scheduling will suggest 4-5 techs a day with that single pharmacist, which is illegal per the current pharmacist:tech ratio laws. I think the Board should set a law for at what point is when pharmacist overlap is required (ie. certain number of rx's per day, certain number of immunizations in a week, etc) as well as potentially increase pharmacist:tech ration to 1:4.
237	Pharmacist to technician and technician in training ratio is often exceeded therefore more difficult to oversee all dispensing transactions. An additional pharmacist during a staff pharmacist's 12 hour shift will greatly improve workflow and patient care
238	Pharmacist to technician ratio should be reduced to 1:2, and employers should be prohibited from hiring cashiers. Employers should be required to hire 1 pharmacist for every 2 technicians on shift instead of sending more cashiers to help with workload. Supervising too many technicians and cashiers can cause more interruptions for pharmacists especially if not adequately trained, and there are too many tasks that only a pharmacist can complete. More technicians are needed in order to handle current workload however it is not helpful without more pharmacists.
239	Pharmacists are overly accessible. Instead of being seen as a resource for medical advice, we are now seen as the store directory and are interrupted constantly by questions regarding product location, complaints about OTC lockups or stock issues, and we can barely process a single prescription without an interruption. Certain chains are even cutting down on non-pharmacy staff with the expectation that pharmacy pick up the slack.
240	Pharmacists shouldnt be working over 8 hours per day. Due to fatigue more medication errors occur. Pharmacies like Costco, CVS and Walgreens have made it a common practice to require pharmacists to work mandatory 45 + hours every week. That is minumum 9 hours a day
241	Pharmacy has become too metric centered and companies apply pressure by constantly sending reminders of targets. The amount of non dispensing activities are increasing all the time without any addition of time to compete tasks. With the introduction of t

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242	Pharmacy tech help and ratio increase. Of course adding a pharmacist would help but I don't think it's realistic that companies could pay. Having any extra help is crucial. Non dispensing tasks need to be deferred to a specific tech/pharmacist. We have n
243	Pharmacy technicians are not compensated for providing vaccinations and putting themselves at risk for needle sticks and significant errors voluntarily without more pay. Technicians need to be compensated for the job they do so turnover is reduced. Turnover directly impacts patient care and more time must be spent to train new technicians, which also affects patients loyalty. More issues can arise it patients do not trust staff and use multiple pharmacies
244	Phone call center
245	Phone calls asking for pharmacist advice should be charged with a fee.
246	Phone calls should be handled by a different team.
247	Please Increase number or technicians and clerks. Please make it a legal requirement for the employer to follow minimum number of techs to at least 2 technicians/clerks per day. There were times we pharmacist working alone or with only 1 tech per day. That was very challenging to ensure patient safety when we had to rush to help eveyone.
248	Please remove non medication services from pharmacy and let pharmacist only focus on patient medication and safety
249	Please require pharmacies staff 2 pharmacists per shift.
250	Post fill audit to do one final check on high risk prescriptions before leaving the pharmacy
251	Prevent a pharmacist from working without a technician and having to receive, transcribe, review, fill, review and dispense prescriptions by themselves.
252	Provide adequate staffing. Smith's needs to increase pay and benefits for technicians to attract more competent applicants. This pharmacy has been working extremely shorthanded for over 3 years. Safety of patients is extremely compromised. Although management says patient safety is the most important, the metrics imposed and pharmacist/ tech hours earned based on metrics show otherwise.
253	Provide enough staffing
254	put more emphasis on doing things correctly the first time an individual works on a prescription
255	Realistic expectations for staffs and Rph's to adhere to: our job can not reflect base on numbers the board should put both the pharmacy staffs health and patient health at their priorities by protecting the healthcare sector equally! Given the pharmacy
256	Recruit and hire more Pharmacists. So , increase the salary and benefits of Pharmacists, which will help in the long run to decrease the turnover rate.
257	Reduce the amount of immunization appointments. Allow us to have at least 1 hour after opening and 2 hours before closing with no appointments to catch up on work or clean up the pharmacy. Reduce the amount of appointments to 1 person per appointment tim
258	Reduce the call volume to pharmacy so staff can concentrate on more urgent or critical tasks.
259	Removal of metrics, more technician help, adequate training
260	Remove corporate metrics
261	Remove metrics especially vaccination requirements. I would love to promote vaccinations without the pressure of a required number.
262	Remove metrics or have extra staff that can complete the needed metrics or items not pertaining to a patient care
263	Remove performance metrics. At least 2 pharmacists each day for locations that fill more than 200 scripts a day
264	removing metrics and increasing pharmacist staffing
265	Removing practice metrics. This is EXTREMELY important with respect to œnon-dispensing services"there should NEVER be time limits/quantity requirements on these direct patient care activities. This only leads directly to patient harm.
266	Removing the metric to answers phone calls in under 60 secs. We have 9 separate phone lines and they ring all the time.
267	Removing value of metrics. Patient safety is more essential than profit.
268	Required that employer provide more pharmacist if they are adding more none dispensing tasks such as immunization, point of care testing, doing diagnostic and prescribing
269	Review number and intensity of government regulations involved in each and every prescription
270	Scheduling overlap and days off
271	Separate area and staff for typing and billing insurance
272	Separate non-dispensing activities from processing prescriptions. Adding more pharmacists would make a huge difference. One could handle prescriptions and the other could handle MTM, vaccines and patient consults and questions. Every hour the pharmacy is open should have a minimum of 2 pharmacists on duty with additional pharmacists added for increasing volume. For example 1 RPh for every 200 Rxs.
273	Set hours to just do non dispensing tasks ...separate from a day of dispensing
274	Sit down station for pharmacists to reduce fatigue
275	Staff Training for new technicians - standardized requirement for training hours Rph overlap with high volume stores to help with counseling and imz

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276	Staffing
277	staffing for pharmacists, techs, cashiers
278	Staffing issues. People don't want to work, they know it's going to be a rough shift because of missing coworkers.
279	Staffing of both rph and techs have been anemic for years. Increase staff & find a way to keep good staff.
280	Staffing to meet patient needs. Most of the time you have multiple areas to assist with only a small number of staff.
281	Staffing, Workload,
282	Staffing,backlog of work,additional responsibilities. We have to stop the mindset of doing more with less. Yes, we have robots and tools to simplify and automate processes but they still need staff intervention to maintain and calibrate.
283	Stop all the Covid shots and all of the testing for Covid. Too many shots. PBMs stole all of the money so now pharmacies have no choice but to do all of this nonsense MTMs, infectious disease testing, vaccinations, just to stay in business. The actual work that we need to be doing (filling prescriptions) is falling by the wayside and patients are suffering as a result.
284	Stop basing performance reviews based off of metrics like verify by promised time, number of vaccinations, number of prescriptions sold, MTM engagement etc. the main focus should be of patient safety and engagement. When the company and higher ups are al
285	Supportive personnel metrics are not equal based on Rx volume. While I believe the company I work for is the best out there and is committed to pt safety and care for their associates, pt satisfaction will always be tied to getting their medications in a timely manor. Other stores which do less volume are allotted more supportive personnel hours. Having more cashiers and techs would improve outcomes.
286	Take away the metrics that leads to unrealistic expectations from the pharmacists.The staffing model that the company is implementing is unrealistic . Pharmacy staff should be treated like a human being not like a filling / dispensing machine. We need to
287	Tech hours. It is extremely unsafe to have a pharmacist work solely by themselves.
288	Technician help is a must at my workplace setting
289	The amount of Rx's that are expected to be filled before days end is excessive. There is constant pressure to meet our metrics that focus on Rxs filled, vaccinations, PCCs (so pointless), and patient surveys where the must indicate they would come back t
290	The amount of staffing they provide. Increasing staff would help with the high workload that is given and expected from us.
291	The biggest issue with retail pharmacies in Nevada is staffing issues and unrealistic expectations from corporate.
292	The emphasis on achieving increases on immunizations, travel medications, hormonal contraceptives and OTC sales growth often comes at the expense of dispensing prescriptions. From August to November, my pharmacy becomes an immunization clinic and completing the 3000+ prescriptions weekly in a timely manner becomes extremely challenging. The attitude that my staff and I "have to find a way to do it all" is becoming common place. I have been in pharmacy for over 30 years, am exceptional at finding ways to expand our practice and meet the needs of our community SAFELY AND EFFICIENTLY. I have been a top immunizer for the company. I have been at the top of the leaderboard for many corporate focuses. The current work environment and expectations tied to corporate goals has put me in a position to decide which goal to achieve: their numbers or patient's prescriptions completed in a timely and accurate manner while supporting my staff in efforts to prevent burn out. This year, with absurd goals, I chose my staff's well being. I was harassed for not being competitive, accused of not caring about my job, and threatened with disciplinary action.
293	The expectation of metrics, volume of prescriptions, control paperwork, vaccinations, and giving great service and being a great clinician is unreasonable. I think the first thing to go is outlawing metrics. Second is hiring more pharmacists. Third is changing the expectations of patients that pharmacists are pharmacy machines.
294	The expectations set by my current employer have raised significant red flags, particularly regarding the review of prescription data and drug utilization reviews. As a remote pharmacist, I find myself pressured to review prescription data within an average of 18 seconds per prescription and conduct drug utilization reviews within an average of 7 seconds per prescription. These metrics are not just impractical but pose a serious risk to patient safety. In the course of my daily responsibilities, I come across numerous errors made by technicians and pharmacists that, in my opinion, could be avoided if we were granted more reasonable time to thoroughly review prescriptions and patient profiles. The current metrics create an environment that prioritizes speed over accuracy, a perilous approach in the field of pharmacy. Moreover, the time restraints contribute significantly to a stressful environment, making it mentally draining to constantly operate under such high-pressure conditions. Patient well-being is our top priority, and the strain to adhere to such stringent timeframes not only jeopardizes our ability to ensure the safe dispensing of medications but also takes a toll on our mental well-being.

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295	The high amount of various tasks required to be completed daily. There is only one pharmacist who has to review (both data entry and product verification) scripts, take verbal scripts over the phone, sign off of new scripts going out at the register, provide patient consultation, performing MTM and new therapy follow-up patient calls, check-in controlled medication orders, verify vaccines (if not giving them), while also backing up the technicians on all their roles (data entry, production, answering phones, running the register) and any managing duties (PIC). Multitasking is required to work in this environment, but it's multitasking that leads to medication errors. That's a lot of things for one person to be expected to do normally, without patient safety involved. A second rph on duty would be the first thing to help with all of these tasks. It's hard to keep up with all of it normally, but especially when you're constantly falling behind. A call center to screen for calls that actually require pharmacy assistance/a call center to perform the numerous outgoing calls we are required to perform. Onsite testing and vaccines are fine, if there is a dedicated person to do them. Having the technicians be able to give vaccines is nice, but they are usually already busy doing their normal technician duties to really be able to help.
296	The number of pharmacists working at a site should never be 1. There should be at least 2 pharmacist, particularly during busy hours.
297	The pharmacist is the neck of the bottle for all tasks, overseeing technicians, counselling, verifying, immunizations, which leads to constant interruptions and multitasking. There is no time to do it all. Have to do this all while being monitored on everything from wait times, verified by promised, immunization goals, calling patients for PCQ/adherence calls in order to make goals and keep your job. Have to work through lunch to get caught up as the prescriptions are still coming in. and stay late an come in early so don't fall further behind. Technicians can help but are barely educated and trained. Therefore turnover is high. Get constant pressure from above, as more tasks are added no additional pharmacists are given. No overlap in order to get tasks done. Pharmacists should not be allowed work "off the clock" most pharmacists have to come in early (as prescriptions are DUE as early as 15 minutes after opening) and stay late as if they have carry over prescriptions can lead to discipline. this leads to dangerously long shifts. But since most pharmacists/managers are "salaried" it is allowed/expected.
298	The pharmacist verifying accuracy and f the scrips being entered and filled does not do any of the other requirements for patient care calls and or mtm
299	The pharmacy reduced the staff pharmacist hours from 40 to 32 and the pharmacy manager from 40 to 36 hours per week with same volume of prescriptions as before. We never get caught up.. running all day.Pharmacists should only do a certain number of prescriptions per hour. Air traffic controllers , doctors have a limit of workload..otherwise mistakes get made . The pharmacy chain corporations are still ending up with high profits after expenses are paid. Allowing more hours to do my job tasks would promote patient education and safety.The large pharmacy retail chains have made it a stressful environment. Money is the bottom line . Pharmacy career has become a big disappointment compared to 20 years ago. Thank you to the board for listening.
300	The pharmacy should have increased # of pharmacist and technician, with a dedicated phone service
301	The volume and pressure to fill 400 to 500 scripts in 1 day by 1 pharmacist.
302	The workload is so intense. Many technicians do not last because the workload is so intense and it's just not worth the money. Meanwhile the one pharmacist on duty is pulled in 6-12 different directions at any one time. Yesterday I had 6 phone calls all
303	There are too many interruptions when reviewing a patient's profile and new orders coming into the pharmacy. Sometimes I have to come back to the same prescription 3 or 4 times when doing data review (double checking what the technician entered with regards to correct patient, drug, strength, dose, directions and physician) More pharmacist hours would allow one RPh to focus on the data review while the other pharmacist could focus w/ speaking to patients and physicians.
304	There is not enough time to finish everything expected of us. A higher tech ratio or requiring a minimum amount of technicians on duty at any given time depending on script count or other factors.
305	There should be another pharmacist in between a 12.5 hour shift of the main pharmacist to help out with the workload (dispensing, vaccinations, MTM calls, verification)
306	There should be designated person for phone calls and mtm, vaccines . Techs and rph must be sufficiently trained
307	There should not be days where pharmacist is left alone for whole day without any technician help
308	They keep adding tasks only a pharmacist can do, but don't provide extra pharmacist coverage. Requiring two pharmacists at all times should help with this. One can focus on dispensing tasks and another one on counseling and non-dispensing tasks.
309	This surgery is exclusively for Walgreens. I worked as both a floater and a pharmacy manager. We do not have sufficient overlap. Many of us go without bathroom breaks, lunches, and 15 minute breaks because the company wants to save money on pharmacists.
310	Too much work load for 8 shifts for 1 Pharmacist (PIC/Staff duty) Need 3 technicians help OR 2 technicians +1 clerk
311	Understaff issues at chain retail are due to unfair compensation for techs. Their pay rate is so low compare to other industries but was expected to have many responsibilities. Even a fast food restaurant pay their cashier better than a tech that has 3 y

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312	Understaffed of pharmacists and technicians, the ridiculous metrics and number of questions at the cash register.
313	Understaffing needs to be addressed. [redacted] pharmacy supervisor for NV, needs to be replaced with someone who will be honest with pharmacists, someone more concerned with hiring pharmacists instead of forcing them into pic positions they don't want, and someone who assists in getting open shifts covered. Technician training programs need to be implemented and pay increased to encourage techs to stay through all the stress of pharmacy. It would be extremely helpful to have more than 1 pharmacist at an open pharmacy so that one may focus on dispensing functions and the other on vaccines/other tasks.
314	Unreasonable metrics/workload. Retaliation. Hostile management / work environment. Erratic schedules lacking work life balance.
315	Until non-dispensing interruptions and non-patient interruptions are eliminated or decreased, NOTHING will change or improve
316	Updated equipment (scanners, computers, filling machines)
317	Utilizing a software system that is completely integrated and not a cobbed array if modules that one must exit and access another portion, obtain an answer, write it down and re-enter is the original field. Simplify.
318	We are not provided with enough consistent technician hours to maintain a proper staff, so technician increase. Removing metrics. Removal of mandatory daily call lists
319	We have a space issue in our pharmacy. Too many bodies filling too many prescriptions combined with an inefficient work flow is cause for errors. Medications are stored in wrong places, too many hands are touching the medications, baskets are falling all over the place, not enough shelving for required documents. Our volume is too high and there's no room to add more technicians, pharmacists, or cashiers.
320	We need breaks, more staffing. Constantly being on œgo go go is mentally, emotionally, and physically exhausting.
321	We need mid shift Pharmacists because 1 pharmacists can't handle 3 cashier, 3 tech, plus phone call from patients with questions concerning their prescriptions.
322	We need more hours provided by the retail pharmacies to staff a pharmacy appropriately. It is unreasonable to have 1 pharmacist 1 technician to hold down a pharmacy doing 200-300+ scripts a day plus vaccinations and all other side tasks including regulatory, and inventory. Retail pharmacy companies need to supply the workforce to have a full functioning pharmacy that meets patient safety needs
323	We need more staffs like pharmacist to help with verify prescriptions and medication, also more technicians to help answer phone calls, ring up customers and help with vaccinations.
324	We need more technician hours and more pharmacist overlap to safely fill all prescriptions for the day. We should be able to schedule as many technicians as it's necessary to fully staff the pharmacy and perform our duties safely. Non-dispensing duties s
325	We need to have our allotted number of pharmacists daily. Most of the time our mid shift pharmacist gets pulled to another pharmacy due to staffing shortages. We also need permanent pharmacists staffing our location. We should have 5.4 pharmacists on staff but we only have 2.
326	Wearing of masks if coughing
327	Well Staffed at all times
328	when i was a pharmacy manager, i voiced my opinion on pharmacy workload was too heavy on annual pharmacy board inspection.
329	While I believe immunization and medication management are essential to patient care, retail pharmacy should not be the primary point of service. Interruptions and increased non-dispensing workload lead to dispensing errors. The level of patient attention is also diminished for non-dispensing tasks because there is not adequate time to spend. Increasing the number of pharmacists on duty when dispensing and non-dispensing tasks are to be performed would greatly decrease medication errors and increase patient care. Allowing Nevada pharmacists to work from home or not within the confines of a retail pharmacy to perform some duties may help reduce workloads.
330	With only one staff pharmacist on duty during a shift during which 400 prescriptions are filled, the expectations are: Clinical Services are discussed and offered to patients; Controlled Substance Stewardship, including detailed reports and contacts with Drs and Pts are documented; Immunizations are given, and we are pressed to do more; the new Test To Treat is being rolled out so that we now perform testing for Flu, Covid and Strep as well and write the prescription for needed medication and dispensing it. This in addition to standard procedures such as verifying Rx's and making sure medications are dispensed accurately.
331	Worked at cvs for a couple years and got burnt out quickly. They don't support pharmacist or technicians. Days at cvs 8819 would at times have one pharmacist fill at least 500-750, some days with one pharmacist and other days overlap for 4 hours. Still s
332	Workload
333	Workload metrics are dangerous, staffing hours need to be increased and [redacted] needs to put people before profits.
334	No response.

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1	**Question 55: What workplace conditions, if any, do you believe should be addressed at your primary practice setting to promote patient safety? What suggestions do you have for improving the condition?**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **a. Institutional/Hospital Pharmacy**
3	**Responses**
4	Adequate breaks for retail folks
5	BETTER ACCESS TO PT EHRS
6	Better communication and training
7	Better communication between management and staff and firm standards that are clear and concise implemented.
8	BETTER EMAR. INCREASED STAFFING. PHARMACIST:PATIENT RATIO REDUCTION (CURRENTLY 1:200+)
9	Better software and computers
10	Better staffing of pharmacists. Less corporate metrics that are not aligned with patient safety, and instead aligned with profitability.
11	Bigger space, consolidating workload on each individual pharmacist, more uninterrupted workflow (the phones!), more staff for the amount of work we do
12	Break time
13	Competant Director who understands the workload and role of staff Rph with experience
14	Compliance with state and federal laws
15	Continue to focus on the work in front of you. Standardizing processes.
16	Decrease patient to pharmacist ratio; have clinical specialists being able to focus on their specialty
17	Decrease phone calls. Have a way to screen non pharmacist questions to technicians
18	Direct involvement of pharmacists in doing medication reconciliation. Provide the necessary hours to perform this function
19	Enough staff to do the work without being constantly rushed.
20	Equally distributing workload, amongst unit base pharmacists
21	Hard to say...the hospital is always trying to reduce safety issues, whether it's pharmacist or technician based concerns (ie, spreading out workload if a job becomes to big for one position, increasing staffing, improving new employee training, etc)
22	Having enough Pharmacists and technicians working. The staffing for the day in the hospital is based off of census. The census for the day is based off of patients admitted by midnight. It does not include the patients that come to the ER(emergency room) and the surgery patients. However, most of the stat medications are from these patients. The staffing should not only be based on census but also on how sick the patients are and requiring stat medications.
23	Having left [redacted] pharmacy at peak of COVID vaccine and testing administration it was difficult to verify prescriptions and maintain safety as the sole vaccinator. Oftentimes I would come into work an hour before my shift was set to begin in order to catch up from the numerous backlog that was left for me the day before. [redacted] notoriously will have one pharmacist work a 12-13 hour shift and expect them to verify 300+ prescriptions while vaccinating, consulting, and clarifying confusing prescriptions from providers. Oftentimes I would work through my lunch and find myself feeling incredibly anxious that I could not provide the level of care or customer service that I wanted to. Having additional pharmacist to complete tasks would have greatly increased work satisfaction and promote patient safety.
24	having managers who actually listen, build quality INTO each process
25	Hiring a cashier/clerk to do the check in and out
26	Hospital corporations should not rely on only the number of patients (œcensus) as the defining factor of how many pharmacist and technicians to staff but they should also account for severity of illness and number of prescription orders requiring veri
27	I think there should be a standard for operating systems. For example, our system is antiquated, it types different directions on the label vs the recording/ checking portion. There should be stricter and more regulated requirements for these systems
28	Improve ease of communications with the Licensed Medical Professional
29	In my previous experience within retail pharmacy, I encountered a multitude of challenges that significantly impacted workplace safety and ethics. The insufficient number of pharmacists and the excessive workload created an environment that compromised safety standards. This situation has led to a collective effort in various states to establish unions, reflecting the growing concern within the industry. One major concern that requires urgent attention is the conflict of interest within the Nevada Board of Pharmacy (NBOP). Members of this board simultaneously serve as representatives for large retail chains while also operating within the Board of Pharmacy. This dual role presents an evident conflict, potentially undermining the impartiality of decisions made. Retail chains are pursuing strategies that prioritize cost-cutting measures over employee welfare and patient safety. There's a concerning trend of advocating for reduced pharmacist wages, increased workloads, and the downsizing of experienced technicians in favor of hiring and training less experienced staff. Regrettably, many initiatives proposed by the Board of Pharmacy seem to align more with maximizing corporate profits rather than prioritizing safer work environments for employees or ensuring optimal patient care

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30	Increase in pay for technicians so we can focus on quality and retaining employees instead of constantly training and losing staff to higher paying jobs.
31	Increase in staffing. Overnight I am the only pharmacist responsible for all admitted adult patients of a hospital with nearly 800 beds. Some days I do not have the ability to take a lunch break. On top of verifying all orders, I also must check IVs, cover the pediatric and ED pharmacists lunch breaks, and answer telephones. A technician dedicated to the phone, like the day and swing shift have, has been requested and denied repeatedly. Even just that one technician would alleviate my tasks and help me focus on patient safety. Requests for any extra staffing is repeatedly denied due to budget and currently we are required to flex and attempt to work short staffed during what is typically the busiest time of year.
32	Increase number of pharmacists and remove nursing management over pharmacists
33	Increase number of pharmacists and technicians. Eliminate entirely metric system in Retail Pharmacy. In the retail setting, one pharmacist should not fill more than 200 Rx a day
34	increase staffing
35	Increase the number of staff.
36	Increased local pipeline of qualified pharmacists
37	Increased staffing based on a set minimum staffing grid. Productivity based on census does not appropriately reflect patient acuity or amount of orders being processed daily.
38	Increased staffing, possibly a requirement for a certain number of pharmacists per inpatient per day
39	It's not that we do not have enough employees most of the time. It's that work related duties aren't aligned the best to get the work done that needs to get done in an unfustrating manner.
40	Lack of pharmacy staffing for both pharmacists and technicians should be seriously addressed.
41	Lack of staffing and additional budget for additional pharmacists.
42	Learning environment , better staffed pharmacists and technicians
43	Making sure there is enough staffing and pharmacists and technicians with the specialized knowledge areas. For example, we need a tech who is Med Rec trained to do that in the ED, we need enough residency trained pharmacists to cover all the auditing, medication, patient safety and regulatory requirements. Currently so much is required that it is hard to balance it all while keeping patient's safe and making the needed interventions and follow up with prescribers to optimize patient care.
44	med rec
45	Medication education to staff including nurses, pharmacists, all providers; EHR system modifications
46	Medication History FTE, Oncology FTE, Antibiotic Stewardship FTE
47	More pharmacist to patient ratio on med surge units and ICUs. Right now there is 1 pharmacist to 100+ patients on gen floors, and up to 1 pharmacist to 36 icu patients, including rounding. With such large workloads, detailed work can just not get done.
48	More pharmacists
49	More pharmacists on nursing units.
50	More QUALIFIED staff, not just any staff hired out of desperation. Proper training, less concern for metrics.
51	More staff
52	More staffing
53	More staffing that are trained properly and motivated to work.
54	My new job is great. No issues
55	N/A
56	N/A. Many open positions for pharmacists with sign on bonus and referral bonus, no applicants.
57	Na
58	None
59	none my practice is safe
60	None.
61	Overall medication and order adherence. Multiple bodies of administration are aware of nursing protocols not being followed in terms of medication use and it is very slow moving to fix them, causing potential risk and harm.
62	Pharmacies should be properly staffed with 1 pharmacist and 3 techs for every 100 prescriptions filled per day. Example 400 prescriptions in a day equals 4 pharmacists and 12 techs
63	Pharmacist to patient ratio
64	Physical conditions can be improved by decreasing the amount of noise Provide enough FTE's to cover the hours needed, also to include coverage for vacations ~ the answer is not to just work short to allow for time off. Decrease constant interruptio
65	Prescribers should get popups for duplications , incorrect dose , nonformulary products. Error is allowed into the system because œ we don't want to bother the doctors œ. The pharmacist is to contact prescribers to notify of the error. But Pharmacis
66	provide needed staff, equipment, technology.

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67	Reasonable workloads for time allotted, less distractions by adding more pharmacists who will focus on different tasks so that each pharmacist will not be distracted much from their primary duty, doctors being required and held accountable for putting a diagnosis on each prescription for less medical errors, doctors being required and being held accountable for cancelling remaining refills on prescriptions they no longer want the patient to take (i have seen many patients taking duplicate medication or the wrong doses), caps on how many rxs a pharmacist can process a day requiring companies to hire more pharmacists depending on how busy they are and/or how many other non dispensing services they provide
68	Reduce the amount of continuing education required during work
69	Replace the current pharmacy software with more user friendly software
70	Retail pharmacy is a disaster. The chains have too much power and don't treat the pharmacists like health care professionals.
71	Schedule more help during busy times
72	Short staffing of pharmacists and technicians. EPIC is often not updated with correct medication builds and this can lead to serious med errors. Suggestions to improve including hiring more pharmacists and hiring an IT/EPIC pharmacist
73	Staffing of highly skilled clinical pharmacists.
74	Staffing. Training.
75	The amount of orders pharmacist have to process in the inpatient setting along with dispensing duties. More pharmacists in the inpatient setting and not allow manager pharmacist hours to contribute to productivity and technician/intern oversight. A law for minimum pharmacist to patient ratios inside a healthcare institution.
76	The primary goal is to get the meds to the patient safely. If we do not have the staff (due to call out etc), we need to cut back on rounding.
77	The promotion of patient safety will be enhanced by education and knowledge.
78	too much reliance of metrics instead of patient safety
79	Toxic positivity from managers prevents staff from speaking up about staffing concerns. More staff to accommodate increased workload. Need to be allowed to scale back services as staffing allows
80	We need to change to less manual paper work.
81	We need to have separate time to do the disease management and clinical pharmacy consults & infusions, rather than having a laptop open with a computer for reviewing scrips and having to go back and forth between the two in order to complete tasks. We used to have separation and would rotate between the office for patient management and going into workflow.
82	No response.

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1	**Question 55: What workplace conditions, if any, do you believe should be addressed at your primary practice setting to promote patient safety? What suggestions do you have for improving the condition?**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **c. Independent Pharmacy** **d. Department of Defense or Veterans Affairs Pharmacy** **e. Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)** **f. Consultant Pharmacist** **g. None of the above, I am currently unemployed or retired.** **No Response**
3	**Responses**
4	1st) thank you for conducting this survey. 2nd) the order for question #47 is the correct order as it is listed in my opinion, so I didn't skip it, I left it in the order it was on purpose, 3rd) the attitude that I pay you a lot of money so I can work your ass off & don't complain is part of the causes of all of our misery as pharmacists. No, there is so much more to that is involved in the task of filling prescriptions in a retail pharmacy than what the bean counters do by looking at metrics of just lick, stick, count, & check prescriptions. There has to be a way for the board to use metrics to say enough is enough for abusing pharmacists. I say 200 rx's/day per pharmacist with a couple techs is enough. 4) I am so sick of hearing about metrics & quotas & could just barf! There is no more such thing as patient care in retail pharmacy. That concept is dead!
5	A push to not encourage a "drive-thru" mentality. We (the pharmacy profession) have shot ourselves in the foot because we push the fact that medications can be given to you in 5 mins or less. The pharmacy community in whole needs to encourage marketing pharmacies for safety and precision and less on how fast the pills get to you.
6	All pharmacists should get an uninterrupted lunch break and time to go to the restroom when needed.
7	DIR Reform, Pharmacy Bill of rights, PBM reform, all so that a pharmacist can help patients instead of getting ulcers about negative reimbursements and keeping the lights on.
8	Divide rph pts equally
9	Drop all sales metric measuring pharmacist performance per prescription filed.
10	Electronic prescriptions and transitioning to all electronic. The amount of time wasted on reaching out to the doctors office to clarify poorly hand written prescriptions would be essential to finishing other tasks. Transitioning to an all electronic system, although some clarification would still be needed, would be a great benefit for reduction in errors from look alike sound alike medications as well as time saving within the pharmacy.
11	Eliminate none licensed personel and hire trained and licensed employees.
12	Eliminate pharmacist distractions and interruptions.
13	Eliminate vaccinations
14	Elimination of metrics, avoidance of mandatory unpaid overtime
15	Employer to allow more staffing during open hours " BOP could help by allowing more than 3 techs per RPh , but ultimately the the staffing œmodels that corporate employs are designed by œ bean counters œ and put too much pressure to perform at
16	Have more technicians
17	Having a call center, or adding technicians
18	Having weekly and monthly staff meetings to address patient safety concerns.
19	Hire more pharmacists.
20	I have no issues with my current workplace; however my per-diem retail pharmacy job definitely needs improved work conditions. The staffing and performance metrics seen in retail are ridiculous and do not allow for patient safety.
21	I retired early at 62 years of age because the retail pharmacy I worked for didn't give us lunch break and the previous retail gave us only half hour lunch break and we don't exactly close on time for lunches
22	I think the number one reason for errors in the pharmacy is being understaffed and not having pharmacist overlap and still having to complete prescriptions within a specific timeframe. This leads to errors and pharmacist burnout because they are not being supported. Retail pharmacies need to staff their pharmacies with more pharmacists which in turn would allow more technician help.
23	I work in close door long term care phsrmacy
24	I'm unsure. I'm sure there are areas to be improved, but compared to retail chain, this is the best place I've ever worked. I have TIME to catch errors/typos, I have TIME to call doctors or to call patients regarding questions I have on their meds. I feel much more diligent/thorough here compared to [redacted].
25	Importance of techs paying attention to patient notes
26	In retail, reduce interruptions while doing data entry, prescription checking, echoing call in prescriptions are very important. Maintaining as much quiet in the pharmacy as possible and emphasizing to techs, techs in training & cashiers their importance in maintaining as quiet an environment as possible for accuracy.
27	Increase ratio of pharmacist to technician

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28	Increased staffing and not putting all job responsibilities on the pharmacists
29	Less interruptions, or phone calls
30	Make transfers easier
31	More direct patient education.
32	more pharmacist which will lead to less interruptions which leads to less errors
33	More pharmacists. We have so many pharmacist-dependent tasks (many not legally required to be a pharmacist, but employer mandated) at my job that are extremely manual and labor intensive and we frequently have just one pharmacist on duty. Sometimes we have 2 pharmacists, which is much more adequate but can still seem like not enough if there are many phone calls and interruptions and new referrals. Our computer system does not allow scanning of medication, everything enters and leaves the pharmacy with manual entry and check.
34	More Pharmacists. Get rid of work metrics. Spend more time filling out time forms than doing a proper patient care experience.
35	More space
36	More techs
37	My primary practice is good, but when I worked for Walgreens full time as a central utility RPH, I brought out concerns of Pt. Safety constantly, they were ignored. I was pressured to verify under 10seconds, and threatened with termination weekly.
38	My work site and position are not in a retail setting however I have many friends that work in that setting and there is a lot pressure to complete all the tasks as quickly as possible with minimal staff, that breds patient safety situations. I have prior extensive experience in institutional settings and staffing is also highly scrutinized, not so much by pharmacy leadership but by those in C Suite positions. Many times those individuals are not pharmacists and have no frame of reference as to what is needed or appropriate. Staffing models in hospitals cannot be based on same metrics as nursing or other departments. There is no real direct conversion for pharmacy productivity in that setting.
39	N/A
40	Na
41	Need pharmacist double coverage to complete management tasks. Another pharmacy technician to help process prescriptions.
42	no suggestion
43	No suggestions for my current workplace. My current job is very fulfilling and why I chose pharmacy. However, I used to work for a big box retail company. The expectations they have on one pharmacist are absolutely unrealistic. When I used to work fo
44	None
45	None and my current practice
46	None at the moment
47	None at this time
48	none right now
49	None.
50	None. Be able to work at your own pace and not be rushed
51	Non-stop demand for more, faster. Eliminate greed driven mentalities and hiding behind the excuse of: œcost of operations.
52	Not applicable
53	Not enough staff. Hire more staff
54	Provide support structure that enables the pharmacist to provide non-dispensing functions the appropriate time to provide direct patient clinical services without dispensing interruptions.
55	Publishing prescription counseling metrics for all pharmacies. For example, at pharmacy xyz 68% of all new prescriptions were counseled by a pharmacist for the past 3 months.
56	Reduce phone interruptions. Reduce paperwork.
57	reduced pressure to process all waiting prescriptions within 15 minutes
58	The biggest concern is the number of technician working. I believe in my DHA/DOD setting that Active Duty Service Members should not be transferred without a replacement. We have had two civilians change jobs and three active duty members transferred overseas since October of 2022 and have just hired two civilian replacements but no Active Duty Technicians to replace the ones that have left. I have 3 people (myself included) running a 7 staff pharmacy. I am doing more technician duties than pharmacist duties after close of business just to keep up. I left a retail job where the last straw was being the only pharmacist on duty from 8 am to 2pm while administering over 100 COVID vaccines plus flu and pneumonia and zoster vaccines.
59	There is biased against employees and managers will discipline employees of their choosing and not reprimand employees who actually caused patient harm.

	A
60	To improve patient care, companies should conisder overlapping pharmacists for 4 hours or more; another option is to have pharmacists working together; lack of breaks/relief for pharmacist is another big problem which increase fatigue in a pharmacist and that increases the potential for errors reaching the public.
61	Treatment of staff in retail chains
62	Utilizing all employees to their fullest capabilities. Ensuring everyone is held accountable for their responsibilities so others don't have take on more work to ensure patient safety.
63	we need more pharmacist to further assist patients. We need to eliminate metrics as those metrics are not in the patients best interest. Metrics are being used by big companies to add additional pressures to pharmacist forcing them to work faster or else that would lead to coaching metrics. Everyone works at a different level of comfort. And there are circumstances arise during a work day that may interrupt those metrics. We are not pharmacists but we are machines trying to beat the clock each and every prescription. If patient's knew the stress we are under and with medications that they're ingesting and the possible errors that occurring on a daily basis. We are only promoting mortality for them and we are not taking the steps needed to better our profession.
64	working on prescriptions uninterrupted with calls, transfers, new phone rx, insurance calls. manditory electronic prescriptions
65	Workload is too high, targets for pharmacy metrics are too high, as these all compromise patient safety. There should also be a mandatory UNINTERRUPTED lunch break for the Pharmacist.
66	Workload left over from other pharmacists that don't complete task or cherry pick. This puts an extreme strain on the pharmacists that are left to complete tasks.
67	No response.

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1	**Question 56: What other recommendations for changes do you have that you believe would lead to improved patient care or patient safety?**
2	**Question 3: Question 3: Which of the following most closely describes your primary practice setting?** **b. Retail Chain Pharmacy**
3	**Reponses**
4	1 hour lunch
5	1. I work multiple locations and practice hours within the same company. I have to address over 800+ scripts during a shift with other services. I work the overnight with heavy emergency room orders. 2. It is harder to help patients in a safe and quality manner the more interactions you have to supervise. (Aka why I am in opposition to increase in ratio) not about extra help. It is the missed opportunities to stop errors and improve patient care. 3. Improved patient care and safety requires the ability to answer patient questions and build confidence. My recommendation is to not change the ratio of technicians to pharmacist in my practice setting. I recommend that no company should demand phone hold time or other metrics/surveys be used in pharmacy as indications. I recommend adequate in store pharmacist staffing by volume. 200 to 250 per pharmacist with minimum of 2 technicians plus 1 if there is a drive thru. I recommend signage to remind patients that we are not a fast food restaurant. I recommend adequate compensation for dispensing presciptions (insurance companies) to afford the necessary staffing. Non-pharmacists should not be supervisor of pharmacists. Zero understanding and training lead to patient safety gaps and decreases in overall patient care needs.
6	1.Ratio rph: tech increase to 4:1. 2. Rx volumes will dictate minimum staffing of : cashiers and tech and rphs that is fair and safe for patients and associates
7	1hr lunch, clocking in and out plus OT pay like California and less Chiefs over the pharmacist . Every boss or supervisor takes time to explain why or why not something can be done . If you cant see that as a distraction then im talking to the wall. If you think I am being overly dramatic you should do a survey asking pharmacy employees 1 question . Have you ever broke down and cried because of work and if so how many times .
8	2 pharmacist minimum per shift
9	2 pharmacists at a site
10	2 technicians to a pharmacist at all times, except within the last 2 hours of the workday where only one may be required
11	A designated employee to give immunizations who is not the dispensing pharmacist. Eliminating metrics that measure productivity verse last year or œplan and constantly leave the pharmacy focused on pushing services instead of safely dispensing medicat
12	A retail pharmacy should be a pharmacy; the pharmacist should not be assigned management of the rest of the store, nor should the store staff have access to the pharmacy at all.
13	A wage minimum for technicians state wide. Clerks at gas stations make more, and techs have peoples lives in their hands. It hard to expect techs to truly care about their profession when the industry doesnt value their role enough to pay them more t
14	œApply online œ doesnt work.
15	Actual private area for counseling. Allowed to close drive-through or lobby service in low staff situations.
16	ACTUALLY FOCUS ON PATIENT CARE INSTEAD OF METRICS AND PROFITS.
17	Added workload=needs more staff.
18	Additional staffing to ease the workload for pharmacy staffs
19	Adequate staff, no increase to the tech ratio (I dont need another person showering me with more work) and 8 hour shifts with adequate breaks. More than 1 pharmacist on duty in any store filling more than 200 prescriptions per day.
20	Adequate staffing. Reasonable expectations. Reasonable and humane pharmacist schedules.
21	Adjust tech ratio to unlimited.
22	Again, I think better staffing is the biggest help.
23	All metric should be removed, they serve no purpose for patient care or patient safety
24	All pharmacies open for more than 10 hours should have three pharmacist scheduled to provide assistance and truly uninterrupted breaks as well as actual time for PICs to handle additional duties required to design, audit, train and implement safety related SOPs.
25	All technicians supposed properly trained to help on any appropriate stations such as RTS, QT, Inventory, cycle counts, not just at the cash register and production. But some technicians are not trained enough on some other stations or do not know how perform particular functions. This raises workload for pharmacist and might impact safety.
26	Allow more staffing and overlapping so that pharmacist can focus on their jobs and avoid interruptions from customers/phone calls.

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27	Allow technicians to ask patients if they would like counseling. While I love talking to patients and going over their medication a large percentage refuse the consult. With all the duties and expectations put on us it would be nice to continue working rather than leaving my station and thoughts just to be told they've had the medication before or they're just not interested. My technicians are capable of offering consultation and then bringing those interested down to the pharmacist. When counseling first started it was novel and patients were willing and wanting to listen, however nowadays most just say no.
28	Allow the pharmacists time to truly consult on a new prescription. We have 2 drive thru lanes and 3 walk up counter lanes. Not able to consult all at once.
29	Allow the PIC to decide how many technicians that they can safely supervise based on practice setting...with technology not all pharmacies operate the same so regulations should not have a one size fits all approach like they do today.
30	Allowing ALL staff to take a break/lunch. Also, designating a person(s) to do non-dispensing responsibilities.
31	Allowing for patients to be able to accept or decline counseling to a cashier or technician or even electronically. Or having a better way of making sure we are only requiring counseling on truly new prescriptions versus new prescription numbers that are linked to a drug the patient has been on long term with no changes.
32	any and all phone items, such as MTM, reminders, refills, etc. no phone at all. it is too hard to handle. get a call center. get a pharmacist to give vaccines or a tech only to do the coals and vaccines
33	Appropriate staffing. At least 1 tech hr per 8 scripts filled in 1 hr
34	Aside for more staffing, we need someone to answer the phone ton ensure that the Pharmacists can answer the phone that is needed by the patient or other medical practitioner that only the Pharmacists can do and also someone will be in charge as the cashier rather than the Pharmacist do it and getting behind to our job as a Pharmacist
35	Being constantly interrupted is the and fatigue are the major problems with patient safety. Having additional pharmacist staff per 11-12 hour shift would greatly help. Also, 1 30 minute meal break on an 11-13 hour shift is not enough.
36	Better behavior from patients
37	Better pharmacy software to catch DDIs more accurately
38	Better scheduled hours for the staff throughout the entire work day
39	Better system esp with CAP counseling with Walgreens intercom. Also need faster speed to get things done faster.
40	Better trained pharmacy technicians...better qualified because training them while dispensing is also very distracting
41	Better training for technicians
42	Better training programs for incoming technicians. It's hard to train a new technician hire on site. It actually takes away from the workflow and available technician help to reach and train, which just creates a more unsafe environment.
43	Better work environment
44	Board of pharmacy should implement how rxs can be done by one pharmacist
45	BOP should further regulate and limit the providers' pain prescriptions to solve the opioid epidemic.
46	Break time
47	Chain pharmacies need to focus less on metrics and more on patient safety. Only way to do that is by allowing pharmacies to have enough staff on any given day to safely fill prescriptions. Pharmacists should not feel obligated to come super early, skip l
48	Clean working environment and better health and safety conditions in the pharmacy. There's not time to clean when processing 600 or more prescriptions a day and our clientele are demanding.
49	Clinical/MTM services should be done by non-dispensing pharmacists. Impossible to do both effectively and safely
50	Close on Sundays Close earlier surprising the week No more 12 hour shifts
51	COMPLETE and ABSOLUTE separation of dispensing services and non-dispensing services. Non-dispensing services are great opportunities for patients but MUST be treated/respected as such, not just another number in a metric.
52	Corporate companies giving the appropriate budgeted hours for pharmacists and technicians. For safety the tech/ cashier hours to rph hours should not be 7:1.
53	Corporate to treat as professionals' healthcare not sales to make them rich.
54	Decrease the number of non-dispensing related activities.
55	Decrease workload
56	designate specific staff for specific task during the shift, reduce amount of multitasking like jumping around from stations
57	directly phone call to provider for rx concerned about
58	Do a script volume to RPH to Tech ratio regulation. At 1 location I did 900 a day with 1 RPH for a 11.5 hours shifts. So basically each script I will only have 46 seconds to verify (assuming I dont do anything else in a pharmacy), so to set a limit o
59	Dont allow unrealistic metrics. Allow enough help for Day to day pharmacy practices.
60	Eliminate metric lead mindset completely..
61	Eliminate metrics

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62	Eliminate metrics , eliminate flu shots goal or immunization goal, provide more technician help will greatly increase patient safety.
63	Eliminate metrics based on volume of prescriptions
64	Eliminate non dispensing responsibilities and the constant threat of disciplinary action if metrics arent achieved or individualize the responsibilities to realistic expectations.
65	Eliminating COVID testing at pharmacies or having dedicated locations, not approving flu testing, increased staffing during flu shot season, improved training, measures to reduce burnout and turnover in staff
66	Eliminating metrics. Prioritizing pharmacist well being.
67	Eliminating vaccines in the retail setting. Eliminating MTMs and phone calls to patients.
68	Employee training
69	Enforcing practitioners to adhere to gdmt. Especially for opioids.
70	Enforcing the counseling laws.
71	Engaging more pharmacist in upper pharmacy management in the companies as against using non pharmacist who do not know nitty-gritty of processing prescriptions and optimal clinical patients' care services .
72	Extra help at least on counter. so tech do data entry , one tech do counting and answer the phone and Pharmacist can focus on verification and counsel rather that filling , typing verification all to gather in rush ,besides doing vaccination or mtm Staffing model is very unrealistic 1 pharmacist 2 techs w,t,f One tech constantly on counter so one tech and pharmacist work inside to everything from order to typing to answering phone , counting , insurance problems etc. constantly in rush and pressure to finish things in suggested time line
73	Extra help for non dispensing related work load
74	Fewer metrics overall. Also, vaccine "goals" should not trump shared clinical decision making for appropriate vaccines for individual patients. Corporate needs to stop trying to make us do everything for everyone. Flu/COVID vaccines? Sure. But is a stressed out retail pharmacy really the appropriate place for pediatric vaccinations? I don't think so. Also you could mandate a way to make them give us the time, resources and help to let us do our jobs and actually talk to every patient like we want to.
75	Finally, I would like to mention the kindness of a pharmacist during practice. The pharmacy manager demanded all pharmacy staff not give any discount to the patient (without insurance) unless they ask because this will affect the profit and bonus of the
76	Fire the manager
77	Focus on patient safety and production quality rather than metrics and bottom line
78	Get back to filling prescriptions. Reform the PBMs.
79	Get rid of metrics.
80	Get rid of metrics. Pharmacists are forced to buzz through drug interaction warnings because corporate and management wants us to finish a certain amount of prescriptions each day.
81	Get rid of the metrics, make greater staffing levels mandatory to be open for business, and level the playing field so that independent pharmacies can be profitable again and increase the amount of choices patients have for where they can fill their pres
82	Getting rid of metrics that our company requires. Let us just attend to our patients, be staffed enough to have conversations with our patients without feeling rushed.
83	Getting rid of the rxom position a lot of times that technician will try to boss the pharmacist around even the store manager will try to boss the pharmacist around but its our license. No one should be able to boss us around when it comes to us making
84	Give more time for vaccines, 10 minute windows is not enough when some patients are new and getting multiple vaccines, inputing insurance info and drawing up multiple vaccines can easily take more than 10 minutes. Less calls to patients for MTM when we barely have time to help the patients within the pharmacy.
85	Give pharmacist more power to reject and modify medication management. MDs now cooperating with Rp
86	good language translation services are required.
87	Happy employees make happy & safe patients. Something has to change, the big pharmacy's are great at promising change & then slowly pulling them away or never even implementing.
88	Have a pharmacist and technician work an hour before the pharmacy opens PAID and get a head start for the day. This time, there will be no interruptions, focusing on dispensing safely. Again, never allow a pharmacist to be alone. Employers should not pus
89	Having a proper workload set by the pharmacy board would enhance patient safety and care.
90	Having a way for pharmacists to better communicate with patients doctor to clarify, discuss prescriptions
91	Having either an extra RPh or tech or clerk

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92	Having more staff to deal with constant phone calls, ringing out / counseling patients, giving vaccines, doing MTMs, all while verifying and processing prescriptions. If retail chains want us to do more, they need to provide more staffing to ensure patient safety and also prevent us from burning out from the workload.
93	Having more than one pharmacist in busy stores
94	Having the PIC have enough time to do PIC workload instead of trying to do PIC workload during a staff pharmacist shift. If PIC is part of the workload for the day but has other tasks, they are constantly getting interrupted which then increases workload for other staff pharmacists.
95	Help with more technician help and reducing non dispensing responsibilities.
96	How long does it take to safely fill 1 prescription ?
97	I believe more help, be it pharmacists or technicians, would have the greatest impact on improving patient care and safety.
98	I believe patient care would be improved if the pharmacist didnt have to administer so many vaccines. There are days when 40-50 vaccines are administered without additional pharmacist help.
99	I believe that there should always be a pharmacist that can just focus on safety, especially for the more complicated patient cases. One that does not run the risk of getting interruptions and has time to thoroughly review a patient and guidelines and m
100	I believe there should be more education on how to maintain health rather than take a pill for everything. Pain management has gotten out of hand especially with the use of narcotics. Doctors need to re evaluate what they are prescribing across the board.
101	I can only think of more labor. Maybe having one or two people that are only focusing on non dispensing activities. I understand the need for these services but they cannot be added to the already overwhelmed dispensing pharmacist.
102	I do not like where these questions were heading with what seems to be leaning toward removing non-dispensing activities from a dispensing pharmacist. Efficiency can be achieved to provide quality patient care but there are fewer practitioners with that capability here. The most effective non-dispensing interventions come from the pharmacists who dispense that patients medications. We have seen a large drop off in the quality of these services when moved to centralized services!
103	I have noticed instances where patients, upon receiving new prescriptions, do not consistently receive the level of counseling that is crucial for their understanding and adherence to prescribed regimens. Patient counseling is a cornerstone of responsible pharmacy practice, serving as a vital means of empowering individuals with the knowledge they need to safely and effectively manage their medications. In the retail setting, where accessibility and patient interaction are paramount, the impact of comprehensive counseling cannot be overstated. Because retail pharmacists often face time constraints and high workload demands, the observed lack of counseling represents a potential gap in patient safety and care. Patients may not be fully informed about their medications, including important details such as usage instructions, potential side effects, and other relevant information that could impact their well-being. By increasing the staffing levels, retail pharmacies can mitigate the impact of time constraints and high workload demands on individual pharmacists. Additional personnel can contribute to a more efficient workflow, allowing pharmacists the necessary time to dedicate to patient counseling without compromising on the overall operational efficiency of the pharmacy.
104	I have to work a whole day shift without a technician. I have to process insurance, Good Rx, give shots, run a cash register and answer the phone¦¦alone! Not safe for patients.
105	I honetsly believe that pharamcists shouldnt be working more than 8 hours in a retail setting. Its go go go like a fast food place from the minute you walk in and creates a perfect environmnet for mistakes to be made. This is also leading to less job satisfaction and pharmacists are just so burnt out that its affecting patient care and their personal lives.
106	I know that you guys have no control over this but if we were able to retain quality technicians in retail it would improve patient safety. But the reality is that they are overworked and underpaid. We are asking them to be immunizers without additional
107	I see multiple filled prescriptions for the same drug on a daily basis and when management is asked about it we are told "yes, but it gets deleted at the end of the day". Any and all prescriptions are entered either by technicians or by an automated system without regard to patient history review. As a clinical review pharmacist we are given seconds to review, fix and/or return Rx's for corrections. It is obvious that Rxs are "pushed out of the queue" just to get rid of it to avoid time spent.
108	I suggest better staffing and advocating support services for the pharmacy team. Cut back on high demands for non-dispensing services (MTM services, immunizations, and point-of-care testing) to focus more on the individual pharmacy teams for better retention. Most people tend to leave due to harsh work conditions (listed above)
109	I think all prescriptions should be electronically from practitioners to pharmacy
110	I think doctors should be required to provide patient's weight, height, and/or lab work that could be relevant to the prescription, especially for children dosing. On inventory day, another pharmacist needs to be scheduled. This is currently not a requirement and we are expected to count all of the inventory while doing our normal duties which is next to impossible so we all end up staying past our paid hours to get it done while the next shift pharmacist is there.

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111	I think that having a minimum set number of technician and pharmacist staff per number of prescriptions filled, that could not be decreased by the employer would be beneficial. I also think that the extremely unrealistic expectations with regard to our metrics needs to change. I got into this to help people, not to be a salesman, cold-caller, or any of the many other, non-pharmacist hats that we are required to wear.
112	I think we should discuss/decide what is a safe number of prescriptions/vaccinations ONE pharmacist can safely perform and staff the correct number of pharmacists. I don't always believe increasing the tech:rph ratio will help. It helps a little but it can also lead to more attention diverted to supervising more technicians. In the end, everything funnels down to the pharmacist.
113	I want mandatory longer lunch hours. At least 45 minutes. We work long shifts, give us a break!
114	I would like to recommend All Prescribes should be sending prescriptions now electronically not just for controlled substances. The fax submission should be eliminated because the ink smears letters and numbers. Examples: 5 may look as 6 or the other way. We have to call and verify each time.
115	I would like to see [redacted] work from home division remove their metrics for reviewing prescriptions and assessing DURs. I understand why work from home requires some monitoring to make sure people are actually working, but they are always on us about making sure we are reviewing prescriptions faster. The department goal is to review a prescription in 16.6 seconds or less and complete a DUR in around 6 seconds. I have zero quality events, am a very dedicated worker (no non-work tasks on company time), and cannot meet this expectation. I'm being threatened with write ups, etc to go faster. I'm a great pharmacist and I shouldn't be forced to review a prescription in a certain amount of time or face discipline. I want to make sure the prescription is safe for the patient. [redacted] rushing us and constantly putting pressure on us to go faster is risking patient safety. Patient safety should come above all else.
116	I would recommend less paperwork required to be printed and kept on file. Pharmacy spaces are crammed full of paperwork for vaccines, prescription processing, etc. It makes it very problematic when we are constantly asked to inventory stacks after stacks of paperwork required by all the different corporate regulations on top of DEA and BOP requirements
117	I would say if the company should be required to staff the pharmacy as the pharmacy manager deems. The people sitting in the office only see numbers and not the total experience we are expected to deliver to the patient. Also computer systems should be required to run properly. If the company cannot fix the issues the system should be removed.
118	If retail pharmacies want to provide clinical services to patients, pharmacists should be required do that in a clinical, uninterrupted setting.
119	Immunizations at the pharmacy is important due to it's accessibiliy. I feel that it really requires a dedicated space and a dedicated staff, if we are to continue to focus on this as large source of revenue.
120	Immunizer should not be part of the workflow or limit immunization.
121	Improved relationships with other healthcare professionals and re-establishment of our profession as doctors of pharmacy. We have become a œswap meet of healthcare¦.we need to re-establish our profession as being the medication experts.
122	Improved response time with providers as most calls go to voicemail or have to leave a message
123	Incorporating a separate entity to perform medication treatment management calls.
124	Increase amount of pharmacists on duty during a shift.
125	Increase in pharmacists/decrease in individual workload. More paid time off would lead to more refreshed pharmacists. Nurses that have a high work load have more days off (usually they work three 12 hour days and have 4 days off) We are easily as high paced as the nurses.
126	Increase number of pharmacist and technicians
127	Increase overlap pharmacist hours and increase technician hours
128	Increase paid rate for technician to reduce turn over (keep experienced technician)
129	Increase Pharmacist Staffing
130	Increase pharmacist to technician ratio. Require all pharmacy technicians get nationally certified.
131	Increase reimbursement from insurance companies
132	Increase staffing with fair scheduling, not to use productivity numbers (and how fast you are) to mentally stress us out. So we dont rush to do things.
133	Increase staffing.
134	Increase tech ratio (4/1) is good
135	Increase technician and cashier help
136	Increase technician to pharmacist ratio
137	increase the number of pharmacists per shift
138	Increase the number of pharmacists per shift.
139	increase the number of techs and pharmacists and offer training hours in addition to tech hours
140	Increase the technician to pharmacist ratio
141	Increased in the amount staff both pharmacists and technicians
142	Increased pay to match current inflation rates.

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143	Increased staff, especially pharmacists. But we also need better incentives for technicians
144	Increased staffing
145	Increased staffing and adequate training time is most important.
146	Increased staffing and directing non-dispensing and non-patient responsibilities away from pharmacists to improve patient safety. Suggest scheduling more shifts or more staff to focus on non-dispensing and non-patient responsibilities.
147	Increasing staff, have mandatory two 15 minute breaks and 30 min lunch and midshift pharmacist to allow this to happen.
148	Increasing technician pay will help retain and attract more quality applicants, which will lead to improved patient care.
149	injections are stressed by cooperate because of profit margin increases from them. Yet no additional staffing, time, or safety issues are addressed for the increased work load. of course extreme pressure is constantly put on the pharmacy to increase injection numbers because of the greater profitability.
150	It would be nice to have another pharmacist on duty to focus more on patient counselling/immunization counselling, therefore not rushing to keep up with the dispensing workload.
151	Just appropriate staffing levels in the pharmacy and stop pressuring pharmacist with ˜metrics.
152	Just fill prescriptions
153	Keep equipment current and in working order.
154	Keep safety items in stock
155	Legal regulations should be made to make sure that no pharmacist work alone with no help. Also, the pharmacist should be allowed to leave pharmacy during lunch break while the gates are closed. We are still required to stay in the pharmacy or in the store building.
156	Less controlled substance volume. Only allowing certain amounts of opioids/gfds done daily because these are very time consuming prescriptions to handle, verify, fill, and put documentation from the doctors.
157	Less interruption so pharmacist can have time to talk with patients, extending lunch hour for staffs (30 mins not enough to have lunch and rest), less non-dispensing service
158	Less interuption to the pharmacist..more staff ..better training for technicians
159	Less metrics especially for non dispensing activities. We need to be able to focus on safely filling scripts in a timely manner.
160	Less metrics expectations.
161	Less workload to be able to actually verify scripts and minimize errors
162	Limit vaccination schedule ,but if the can schedule more help Like Cashier or tech we can do vaccination
163	Longer breaks, 30 minutes isnt sufficient.
164	Maintaining 3:1 tech to Rph ratio and encouraging staffing to be 1 Rph (8 hour shift) for every 200 prescriptions processed to ensure safety. (Eg. 500 prescriptions = 2.5 pharmacist shifts)
165	Making it mandatory for more than 1 pharmacist per shift for every 300 scripts per day.
166	Mandated breaks
167	Mandatory 1 hour lunch to prevent burnout.
168	Mandatory meal lunch for all pharmacist
169	Maximum # of prescriptions that can be filled by one pharmacist. Metrics that are used to push speed over safety. It is all about the #'s not safety. Retail pharmacy is not set up for safety, but getting the most out of each employee: Each employee at the pharmacy is expected to multitask(answer the phone while typing or filling, ring out customers and run back to fill, or type. Pharmacists are giving immunizations then running(literally in some cases) then verifying prescriptions answering the phone and running to do a new drug consultation. All being monitored and timed.
170	Maximum 8 hour shift for pharmacists and treat anything extra as overtime just like in California, so that retail companies would ensure having two pharmacists present each day. Eliminating metrics would drastically help with patient safety as well becau
171	Maybe starting for, and paying for, shifts that begin before opening. It can allow a good start on the day to not feel like you are starting the day already being behind on workflow and then having things pile up as the day goes on. Emploers could reduce hours that the pharmacy is open, but still have the employees work, closed door, to get good uninterrupted work done which would increase focus and safety.
172	More adequate cleaning of pharmacy interior and exterior and the onboarding of more experienced pharmaceutical technicians.
173	More effective text and messaging capabilities rather than phones
174	-More guidelines/requirements on staffing (ie when multiple pharmacists on required, staffing/labor requirements) -No metrics -Requiring cashier options (ie some companies do not allow cashiers whatsoever and really should be required to create systems that allow for cashiers)
175	More help
176	more help with non pharmaceutical help such call center to help with non stop phone calls

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177	more patient understanding md tells patients their script will be done in 20 mins without checking ie if it's in stock if we are at lunch or even not open yet or multiple controls being filled early and we say no after checking pmp and calling Dr back only to leave a message as they are completely unaware 120mme or that is 12 days early.
178	More pharmacist on duty
179	More pharmacists in same shift.
180	More pharmacists per shift in a 24 hour store.
181	More pharmacists required to be staffed
182	More pharmacists should be staffed in pharmacies that have high demands. It is dangerous for one pharmacist to handle >300 prescriptions and supervise > 3 technicians during a shift.
183	More staff
184	More staffing
185	More staffing all around, but must hire 1 pharmacist to every 2 technicians. Safe measures must be taken so that employers cannot find a loophole and just hire more technicians or cashiers without additional pharmacist help. Pharmacists should be able to complete non-dispensing roles without the pressure of meeting metrics for dispensing. Employers should be required to have different pharmacists completing different tasks rather than having one pharmacist complete dispensing roles as well as non-dispensing roles. Employers should have clinical pharmacists on staff to complete non-dispensing roles such as immunizations, patient education (diabetes, smoking cessation, PrEP/PEP, contraception), MTM, and all other tasks that require more than 10 minutes of undivided attention from pharmacist. Employers should be prohibited from requiring dispensing pharmacist to complete any tasks that will take away from processing prescriptions and providing first fill consultations.
186	More staffing that companies must adhere to (provide hours). If we had enough staffing throughout the day, the pharmacist can truly focus on patient care. Increasing the number of techs we can supervise as an rph will not change the problem of the compan
187	More staffing with both pharmacist and technicians. Less metrics and that alone I feel will make huge strides in employee turnover and create less stressful work place environments
188	More staffs
189	More support from pharmacists and technicians
190	More tech help
191	More tech help required, pharmacist should not have to work alone, extend their to fill prescription
192	More tech hours
193	More techs
194	More techs or clerk help at the counter
195	More than 3 technicians per 1 pharmacist should be allowed.
196	More than one pharmacist on duty at a time. Well trained support staff
197	More time for counseling, I feel rushed to get to the next patient
198	More time for patient counseling ergo more pharmacist hours.
199	Move all waiting areas far away from hearing and watching all patient interactions
200	Multiple pharmacist on duty.
201	N
202	N/A
203	Na
204	Needs to remove CLIA services from the pharmacy which is affecting and delaying patient getting medication due to pharmacist is busy providing CLIA services.
205	No metrics or goals
206	No pressuring for metrics
207	Non dispensing activities have to be a dedicated task and should not be required to be completed between processing prescriptions
208	None
209	Not allowing customers to verbally abuse pharmacy staff.
210	Not allowing other store departments (deli, bakery, etc) to use our profits to cover their loss in sales, causing pharmacy to have to cut available tech hours even more.
211	Not doing immunizations
212	Not to focus too much on non pharmacy related tasks and numbers.
213	OTC recommendations from non prescription customers are a nuisance when trying to deal with our own patients prescriptions. Also, because of our relationship in the community, we have patients that come and take up our time counseling on prescriptions th
214	Outlaw metrics

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215	Outsource refill calls, delivery orders.Eliminate covid/flu testing at retail pharmacies
216	overlap pharmacists
217	overworked/harassed pharmacists = deadly mistakes
218	Patients getting tested for diseases in a place that can also treat them if they were in fact positive.
219	Patients no longer respect the work we do. Our employers have reduced the profession to a glorified cashier. When people walk up to the counter they don't understand the importance and the magnitude of the work we do. They expect quick service and our employer demands it through metrics and unrealistic expectations. Vaccinations are something we are expected to promote without any consideration for patient safety. Appointments are scheduled at all times of day and night and regardless of staffing levels. Feels like we're just throwing darts when vaccinating and just billing insurance, ringing up people, and listening to complaints.
220	Patients over profit
221	Patients should be more realistic about their expectations we deal with insurance rejection daily and we could not find enough people to help resolve insurance and they want the pharmacy to bring in more scripts make more calls give more immunization! Pl
222	Penalizing pharmacy supervisors and companies harshly
223	Pharmacist overlap Dedicated Rph or tech for vaccines Dedicated Rph for calls and mtm
224	Pharmacists do not have time to drink water. I remember once mentioning to a pharmacy manager that Im trying to remember to drink water more. She said- but how can you drink water? Because then youll have to go to the bathroom and you dont have tim
225	Pharmacists have been forced to stay and work without pay in order to keep up with workflow and keep conditions in the pharmacy "adequate" to care for patient safety. It has been an open secret in the industry for decades. Due to fluctuations in the current economy, pharmacists' pay is now decreasing rather than increasing, leading to a crisis point in the industry.
226	Pharmacists or technicians whose primary job is everything except dispensing.
227	Pharmacy employees need to feel valued by their employers. Taking care of your staff goes a long way for workplace productivity. [redacted] pharmacy was the BEST company I ever worked for. They took care of us and no one ever left. The minute [redacted] bought [redacted] out, everything went downhill.
228	Pharmacy guilds,chains respecting pharmacists,board inspectors surprise visits to problem stores unanounced ti see what really goes on
229	pharmacy need more staff or eliminating metrics
230	Pharmacy staff cannot legally work until they clock-in and receive pay. This will prevent pharmacists from arriving early to work several hours early to catch up while being off the clock. This is often abused by district managers, who knowingly have their employees come in early off the clock. A possibility of how it can be enforced is to make it a legal requirement to clock-in after logging into a computer. I wish there were better ways to enforce this.
231	Pharmacy technician pay needs to be increased,so that the best can be recruited.
232	Please expand technician to pharmacist ratio, Increase number of technicians allowed per day, please add the legal minimum number of 2 technician required per rph as a requirement so that the employer would not allow to cut technician hours too low. Please also increase technician pay. They deserve to get pay $18 minimum with this type of setting.
233	Please require pharmacies staff 2 pharmacists per shift.
234	Pls remove metrics
235	Provide enough hours
236	Pt safety starts with enough help. Having 2 pharmacist on duty is a huge help even if the overlap is only half of the day. There are simply too many questions or situations that need to be resolved by RPh which being alone definitely leads to interruptions and distractions.
237	Putting a cap on how many vaccine appts per hour.
238	Read above
239	Reduce the amount of phone interruptions in and outbound. Allow pharmacists the right to deny disruptive patients like a doctors office will by severing them from the practice.
240	Reduce the metrics or the expectations the company is using to measure performance. It's a lot of pressure to try to get 80% of prescriptions out on time, expecially when your averaging 400 rx a day w/ no pharmacist overlap.
241	Reducing pharmacist to tech/ cashier ratio back to 2 to 1
242	Reducing pressure to immunize and pressure from district managers to speed up workflow while also managing other tasks
243	Refer to question 55.
244	Reform or eliminate third party insurance. The technology is there
245	Regarding to patient care and patient safety, working with a super busy pharmacy, we absolutely need to have at least 2 pharmacist to counseling & answers all the questions related to the therapy.

	A
246	Remote verification should be addressed. My company allows pharmacists in other states to review rxs and I have found countless errors they have approved upon product verification in the store. If I did not look back at the hardcopy for every single rx I physically check at product review, the errors would have been dispensed. And at that point the NV BOP would not be able to discipline the pharmacist that is responsible but licensed in another state. The workload placed on me requires me to use remote verification but if I had more help I would be able to not use it.
247	Removal of pharmacy metrics
248	Remove customer service surveys as a factor of how good a pharmacist is. My employer wants every Rx to be filled in 10 min or less if patient is waiting in store regardless on how many Rx has been dropped off . Fearful of a bad customer service we have to work super fast. Total time to prepare RX under 5 min . We should not be pressured to multi task . Answer the phone , while preparing vaccines and verifying Rx all at the same time
249	Remove metrics from retail pharmacy.
250	Remove metrics or unrealistic metric goals
251	Removing metric based performance review processes would put the focus back on safely dispensing as opposed to dispensing quickly.
252	Removing ridiculous goals
253	Removing the requirement for digital enrollment, auto refills, mtm and specialty refills. Everything we do is a metric and is monitored. This all takes away from patient care and safety.
254	Require at least 1 pharmacy technician be staffed during all open hours
255	Require call centers for patient requests
256	Require more pharmacist overlap Give more tech hours Require certain amount os scripts per rph
257	Respect for Pharmacists and eliminate the chaotic work environment.
258	Retail chains are cutting hours and increasing workload on all staff to the determinant of patient care.
259	Review protective PTO policy for techs, they can call in anytime even right before the shifts and come late too
260	See #55. Substitute insurance for government.
261	See above
262	Significant education and additional training. Gaining experience as a new grad pharmacist should come with less potential for patient harm.
263	Space is an issue--We are currently performing Clinical Services in a makeshift 5'X3' booth next to the bathrooms at the [redacted] Market. Something more accommodating and sterile not to mention more comfortable for Patients would be welcome by all.
264	Spending adequate time counseling patient on new medications. Give patients an option to text or email on questionable use of medications, directions, dosage and side effects.
265	Staffing
266	Stop MTM, disease testing by the staff in retail stores.
267	Stop putting us on time limit to fill prescriptions .
268	Stop the majority distraction of pharmacist, for exaple cash registration and phone calls activity
269	Stop treating us like we work at McDonalds.
270	Take away goals and metrics for vaccinations. We spend so much time pushing vaccines, that we wear ourselves thin with other tasks. Everything gets backed up because I dont have any immunizing technicians on site. Pharmacist only things like consultat
271	Take out the metrics, lessen non-dispensing duties for pharmacists.
272	The board should get feedback from rph using their personal email and not the work email. The rph needs to feel free to express themselves.
273	The board should require that those none dispensing tasks should require one pharmacist doing only that particular tasks especially for those pharmacies that are doing more than 200 scripts per day.
274	The design of the pharmacy needs to change. We still need to be accessible but there should also be an area the isn't accessible to everyone so no interruptions
275	The greatest safety concern that should be implemented in all retail pharmacy settings is the minimum number of tech hours employers must be required to give pharmacists based on the number of prescriptions filled in addition to providing services and vaccines. It will not make a difference whether 3 or 4 technicians are allowable under one rph supervision if the amount of technician hours your company allows you to schedule in a day is 10-20 hours. The real issue is not how many technicians you can supervise safely, but how many technician hours are actually given to you to complete the workload and goals that assigned to you. Any workload requires the number of hours to complete the work; the number of people is useless without the hours.

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276	The number one thing that would help me was if my company gave me more technician hours. Having one technician per day simply wasn't enough. Also, the stress of having metrics and upper management holding you accountable needs to go away. I would love to have been able to take a break or lunch without fearing falling behind even more. A pharmacist should never be scheduled alone in a pharmacy. If my prescription volume was higher, I would say that having pharmacist overlap needed to happen.
277	The ratio of techs + cashiers to 1 pharmacist should be 4 or less. There are days when my tech to pharmacist ratio is 1:8 for several hours during the day. Many times when I do have a 2nd pharmacist, if they get pulled to work at another store for a sick call out, then I work a 12 hour day with 1 pharmacist 8 techs/cashiers, 4 opening 4 closing. However if I didn't have that many techs the whole operation would be in jeopardy of collapsing. If even 1 tech calls in sick it takes 2 to 3 days to catch back up. That happened this week, one tech called out on Wednesday, another tech came in part of the day to cover, but due to that and high volume of new prescriptions the last few days today (Friday) when I left at 2pm we had 300 prescriptions still to fill from Wed-Fri, not counting the 200+ that the prescribers probably would be sending in before they left for the weekend at 4pm. Then if today was anything like last night, there would be a lot of acute medications coming in from the urgent care and prescribers due to a lot of respiratory illnesses going around the town. It is a recipe for failure, or misfills, or patient harm.
278	The retail chains have too much power over pharmacy. The business metrics are now more important than patient safety.
279	there is no way for a pharmacist to meet corporate standards or metrics when being forced to work solo; MTM phone calls, immunizations, patient dialogue is strictly compromised when forced to answer the vast majority of telephone calls, being forced to f
280	There is not a 'one size fits all' approach that will resolve this problem. The practice at one pharmacy is far different than another. This is true within the same chain as one pharmacy located near a hospital will deal with far greater new and complex Rx's vs. a pharmacy within the same chain located in a suburban residential area, which will primarily deal with well established pt's and primarily refill Rx's. Extrapolate this to closed-door pharmacies, hospital pharmacies, compounding pharmacies, etc. and the 'one size fits all' solution becomes woefully inadequate to address the profound variability of workload and safety issues facing pharmacists and pharmacies. The chains and privately owned pharmacies will give you various cost reasons as to why they cannot accommodate increased pharmacist staffing however, they did not hesitate to jump on the $4 Rx band wagon over a decade ago. Given this fact alone, the argument is without merit. The simple fact is they have calculated what is the acceptable financial risk they are willing to accept to maximize profits at the expense of pt safety. I am in no way saying we should eliminate all the risk. This would be impossible and financially astronomical. But there is however, an ideal place where the risk to the pt is appropriately mitigated and we are currently nowhere near that as of today. Some representatives from both the Retail Association and some chains would like to tell you the simple fix is just eliminating the tech ratio. They provide supposed studies and statistics from other states such as Arizona. Let's address the Arizona study first: it does not exist. [redacted] the former Executive Director admitted this to be the case after he retired. As to the increased ratio, most pharmacies in Nevada are not operating at the current allowed ratio of 3:1. In most cases it is 1:1 or 2:1. Arizona which has no ratio limit sees the exact same. Most pharmacies rarely ever exceed 3:1. The key to remember in all of this is that the pharmacist IS the rate limiting step in the operation of the pharmacy. For good reason. Increasing the number of people they must supervise will funnel more work to the pharmacist further compounding the problem. I have seen it first-hand. This is the profound challenge facing the Board when crafting such regulations. How does one craft a regulation that is broad enough in scope, yet tailored to adequately address the various practice settings? It wasn't until the Colgan Air disaster that the FAA finally addressed a very similar conundrum but unfortunately, the 'wrong' people (politically connected) had to lose their lives in order for this to happen. Commercial air travel in many ways is like operating a pharmacy: airplanes and operations come in many shapes, sizes, and provide a wide range of services with the responsibility for the safe operation ultimately falling on the shoulders of the PIC. In this case, the Pilot In Command; better known to the public as the Captain. In the absence of the Captain, this falls to the first officer. There is very much a direct correlation to the practice of pharmacy and commercial aviation. If an agency such as the FAA could get this done through the creation of the complex regulation known as FAR Part 117, pharmacy Boards should be equally adept in crafting something very similar. The template has already been created and we shouldn't have to wait for the 'wrong' people to lose their lives before something is finally done.
281	There should be 2 Pharmacists on duty overlaping shift at least every Monday and Tuesday. Workload & Productivity metrics and quotas of immunizations is stressful, with 1 or 2 technicians help only. There should have a clek or cashier to avoid too much Interuption in workflow.
282	There should be a limit on number of prescriptions per pharmacist
283	There should be a minimum amount of overlap between pharmacist working per day (not zero)!
284	There should be a minimum number of techs required to work in a practice setting based on volume
285	There should be requirements of how many pharmacist should be staffed, And also technicians according to volume of prescriptions being filled

	A
286	To enhance patient care and safety in pharmacies, addressing several critical issues is imperative. The most pressing concern is the unrealistic metric standards set by corporations, which significantly impact patient safety. These metrics often prioritize speed over accuracy in prescription verification, creating a high-pressure environment that can lead to errors. Revising these metrics to focus more on the quality and accuracy of prescription verification is essential for improving patient care. In addition to adjusting metric standards, streamlining the hiring process and boosting recruitment efforts for pharmacy technicians is crucial. The current complex hiring procedures can be a deterrent, leading to staff shortages. Simplifying these processes and actively recruiting more technicians would help in adequately staffing pharmacies, thus distributing the workload more evenly. Furthermore, providing more technician hours is vital. Many pharmacists currently find themselves multitasking and handling multiple roles due to inadequate staffing. By allocating more hours to pharmacy technicians, pharmacists can focus more on their primary responsibilities, such as patient consultation and medication management, enhancing both patient care and safety. Implementing these changes, starting with the revision of corporate metric standards, followed by improved hiring processes and increased technician hours, would alleviate the pressure on pharmacists. This approach would create a more efficient and safer environment for patients, leading to significant improvements in patient care and safety in the pharmacy sector.
287	Transfers from one pharmacy to another can be a difficult, long process because the out-going pharmacist is too busy to answer the phone to do a transfer. We need an approved electronic or fax request that can be sent from pharmacy to pharmacy. I should not have to wait 45 minutes on hold to speak to a pharmacist to transfer prescriptions or transfer profile
288	Until Pharmacists have more control of pharmacies nothing will change
289	Upgraded software
290	Vaccines, especially travel vaccines and,birth control prescribing require alot of time that take the pharmacist away from dispensing for a good amount of time
291	Very important to provide meal breaks for pharmacists because they have a lot of responsibilities. Working for 7-9 days straight and providing only 1 day rest leaves room for mistakes. Pharmacist is extremely exhausted and needs enough days or rest to recuperate from the straight days of work and Walgreens tries to separate days off to make sure RPhs are working more hours than resting
292	[redacted] uses off site pharmacists to validate rxs, which has become the excuse for eliminating on site help. These pharmacists do not help with the hundreds of consults that may be necessary per day. Many errors have also been found with their verifications. Many errors have also been found from the [redacted] central fill facility, along with pharmacies being unable to keep needed medications in stock and ONLY being able to obtain them from the centralized pharmacy. As a result, proper and timely care is extremely diminished. The call center is also a hot mess. Patients are often given incorrect information and transferred to staff in store without proper introductions or bridges and this leave the patient and staff members frustrated. [redacted] only cares about profit and the level of care over the years has SIGNIFICANTLY diminished. They may say they don't review based on metrics, but in the end it all factors into reviews. Leaders in the front end of the store have been given titles without proper training and have no idea what's happening in pharmacy. Leaders for [redacted] in Las Vegas do not care about staff, which is why many staff members participated in walk outs in October. Due to so many centralized services, pharmacists on site often have no idea what is going on and out of the pharmacy. Corporate employees are extremely disconnected from what happens in store, coming ay employees to preach or discipline them, but have no idea how to put any off what they preach into practice. Several leaders are also backstabbers, talking poorly about employees to others. We also had a store manager who we believed was drinking on the job, but he was never really investigated. It seems these things all get brushed under the rug. More and more is constantly expected from employees, but corporate never gives back.
293	We have been keeping asking for Flex systems back. They only give us 2 months and takeaway. We cant keep up
294	We need a MANDATE to require corporations to staff with a MINIMUM of 3 techs to open/close per day. A MINIMUM OF 3 TECHS AT OPEN AND CLOSING EVERYDAY!!!! We have an IN window, an OUT window, multiple phones constantly ringing, vaccines galore. Vaccines are corporate scheduling of 20 vaccines every 15 minutes NO JOKE during flu season. 20 VACCINES EVERY 15 MINUTES and REQUIRING us TO WALK IN anyone that requests as well. AND NOT TO MENTION THE COPIOUS AMOUNT OF BILLING AND REBILLING TO MULTIPLE DISCOUNT CARDS AKA GOODRX.
295	We need more power to turn away excessive amounts of opioid prescriptions. Must constantly tip toe around conversations and hope a complaint is not submitted. If we accepted every opioid prescription/patient that calls here or comes in daily¦wed be se
296	We need requirements for breaks, a fully staffed team of pharmacists and technicians. If a store is offering other services such as immunizations, we need to always have a second pharmacist there to handle those patients and issues separately. We need da
297	We need security at every pharmacy and we need to have a pharmacist never left alone

	A
298	We should have more paid offstage hours. It is hard to take care of administrative and clinical duties when you are always in need for dispensing responsibilities. We should also be able to be staffed before opening to public and we should have the autonomy to adjust schedules bassed on individual store needs. Patients have different patterns in different neighborhoods. i should be able to make the right business decisions for my team and my patients especially since it is my name and my leagal responsibility.
299	We were given a 30 minute break for lunch and supposed to have 2 breaks in between but never able to take breaks due to the workload . We need extra / enough help fulfill the demand in the retail pharmacy. What happen to the 3 techs to 1 pharmacist ratio?
300	Work hours should be adjusted for pharmacists, like an overlapping schedule or shorter work hours. Additional pharmaceutical technicians but no additional pharmacists may lead to more medication errors. More problems may be caused bh too many staff to supervise
301	You should have 1 pharmacist verifying prescriptions, 1 pharmacist product verifying medications another pharmacist to counsel on prescriptions and making sure lunches and breaks are being followed, 1 pharmacist to handle doctor calls, transfers and other duties that include ordering meds and handling the other functions that are required of the pharmacy (Legal requirements and also Corporate requirements) ex. Inventory, audit and waste.
302	No response.

	A
1	**Question 56: What other recommendations for changes do you have that you believe would lead to improved patient care or patient safety?**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **a. Institutional/Hospital Pharmacy**
3	**Reponses**
4	2 lane drive throughs should be outlawed.
5	Adding clinical activities that complement dispensing, to provide high level of care. For example, having a separate pharmacist to consult and provide flu shots, while one pharmacist focuses on dispensing safely.
6	Adequate reimbursement for non-dispensing pharmacist services. Consideration of limited tech check tech activities to eliminate need for unnecessary pharmacist oversight (cart fill activities)
7	Adequate staffing and better pay will decrease the turnover of staff , hence improving patient care and safety.
8	As someone who has worked in both retail and hospital setting in the past 3 years, the biggest issue I have seen across the board is staffing. Many colleagues are trying to leave the field of pharmacy due to feeling overworked to the point of burnout. It
9	Basically more staffing and mandatory breaks and that is a pipe dream.
10	Better communication between corporate and the pharmacy staff
11	Better communication between management and employees
12	Better physicians
13	Care should be given that
14	Change productivity metrics that reflect pharmacy practice not census
15	De-centralized pharmacy model. Adding a patient safety pharmacist, not using another pharmacies EPIC program or hiring an informatics pharmacist on site. IV team instead of a different person everyday
16	de-emphasis on metrics
17	Duties keep being added without additional staff . Anticoag , electrolyte, renal dosing, med rec , off site emergency depts , etc Limit prescriber drug selection to formulary stock .
18	Eliminate non-dispensing services that can be done in an actual provider setting
19	ELIMINATION OF ANY METRIC NOT DIRECTLY RELATED TO PT CARE, INCLUDING VACCINATIONS
20	Employer would review the daily task and try to estimate the reasonable time required
21	Establishing reasonable staffing levels for pharmacists based on prescription volume is crucial. Implementing thresholds that require additional pharmacists on duty during peak prescription levels can alleviate workload stress and improve patient safety. Increasing technician wages to ensure competitive compensation is essential for fostering long-term commitment and expertise. This step can elevate the quality of service and retain experienced technicians. Revising or eliminating excessive metrics that primarily prioritize profit over patient care is pivotal. Emphasizing quality of care and safety rather than solely focusing on metrics can lead to better outcomes for both patients and staff. Shifting decision-making processes from a top-down approach to a ground-up model is imperative. Allowing input and involvement from frontline pharmacy professionals can lead to more effective and practical solutions that address the actual challenges faced at store levels. Enabling retail pharmacies to have a voice in legislative changes that directly impact their operations is crucial. Providing avenues for retail pharmacy stakeholders to vote or contribute to proposed legal modifications ensures that laws are shaped with consideration for real-world implications rather than abstract intentions.
22	Fewer budgetary constraints with pharmacy.
23	Focus on the patient first instead of the bottom line
24	Hire more pharmacy technicians to help answer phones and complete simpler tasks so pharmacists are not constantly interrupted while processing orders
25	Holding corporations accountable for the mistakes they force their employees to make to keep up with work load.
26	I work in hospital setting¦ our computer system is hosted by a larger facility and we have no autonomy to make changes in this system, which has lead to multiple patient safety issues. This model is a significant contributor to increased errors amd nega
27	If the diabetes management is going to be billed as clinical pharmacy consult, it should be done by a pharmacist, not nurses, who then ask the pharmacist about the billing and refills, as if that is managing or consulting anything.
28	In retail settings that I have worked definitely get rid of matrix. Companies should not tell you how long it should take to get a script out vs patient safety.
29	Increase number of pharmacist per shift and perhaps reduce shifts at high volume stores from 12-13 hours to 8.
30	Increased pharmacist technician ratio for HOSPITALS only
31	INCREASED PHARMACY STAFFING IN BOTH TECHNICIANS AND PHARMACISTS THAT ARE COMPETENTLY TRAINED FOR VARIOUS TASKS THROUGHOUT THE HOSPITAL PHARMACY
32	Increasing the number of pharmacists would lead to improved patient care/patient safety. Pharmacist will focus on one area at a time such as immunizations, MTM, and processing prescriptions. Pharmacist can also focus on clinical activities to help improve patient safety.
33	Inpatient pharmacists to review all discharge medications upon discharge.

	A
34	input from the hourly workers - dont really feel anyone listens to what we say -
35	Less interruptions
36	Less pharmacist involvement with USP 797 and 800 and more involvement with clinical functions
37	Lessening non pharmacist duty while on shift
38	Limiting the amount of techs a pharmacist may supervise at a given time. Supervising more and more technicians without additional pharmacists to help only compiles the problem onto individual staff pharmacist. Interruptions also come from technicians to take care of problems they cannot and should not solve (ex clinical judgement).
39	Making it mandatory for companies to exhaust the pharmacist to tech ratio with every shift is each pharmacist is fully processing over 200 prescriptions. There needs to be increased industry standard base pay for pharmacists and technicians in order for people to stay motivated to be used like mules with no end ever in sight.
40	Meaningful reduction of alerts- Pharmacists get alert fatigue
41	Minimum pharmacist / tech staffing required for hospital bed size - independent of census. There have been times where census is so low, but we could not cut staffing further for fear of patient safety & care.
42	More pharmacists, eliminate metrics. Focus on patient care.
43	More respect and collaboration with physician partners. Less drug shortages.
44	N/A
45	Na
46	New graduates and pharmacists are not receiving a salary or the hours they require to live and pay their student loans. Pharmacist salaries have not kept pace with the work and inflation. It causes pharmacists to work multiple jobs and shifts, compromising their health and preventing them from providing better patient care or acquiring up-to-date knowledge.
47	No metrics. No timed filling of scripts.
48	None
49	Northern Nevada needs more formal pharmacy technician training programs to meet the demand. May be the state board could help in reaching that goal?
50	Not increasing technicians technician to pharmacist ratio and enforce this in institutional pharmacy. Technicians have limited scope with their license and everything they do is the ultimate responsibility of the pharmacist. It is unlikely the amount of oversight for patient safety is optimal with current ratios let alone increasing ratios. With the expectation of pharmacists doing more than dispensing and processing prescription orders and complexity of medical care now there just simply needs to be more pharmacists staffed. Equivalent sized or even smaller institutions outside of Nevada have sometimes twice as many staffing/clinical pharmacists than Nevada institutions.
51	On yearly inspection take closer look at condition pharmacy counter space pharmacist work stations general room in pharmacy also competency of director to be in that postion
52	Our institution absolutely needs to allocate money into hiring more pharmacists. Specialty pharmacists are responsible for orders and clinicals outside their specialties and causes increased work loads.
53	PCC computers from LTC facilities to help assess patients care
54	Pharmacist rounding is good (improve patient safety), but not at the expense of getting the meds to the patients,
55	Pharmacists should not be forced to choose between breaking the law and keeping their job. This is a struggle in all institutional settings due to reporting to non pharmacists. A pharmacist reporting to a nurse is an extreme safety concern
56	Pressure from employer for time spent on counseling calls, after call time, metrics
57	Purchasing more premade/commercially available products.
58	Recognition of the immense value of the pharmacy team from the overall C-suite etc.
59	Reducing the amount of national drug shortages. Continue effects to attract high quality technician candidates.
60	Remove additional MTM responsibilities from the retail pharmacists. Have more staffing for any vaccine seasons or clinics.
61	Remove productivity metrics
62	Review current patient medication profile before dispensing
63	See above
64	Showing your pharmacists that you value them! Leadership
65	Somehow eliminate the "insurance" time suck.
66	Technicians need to answer and triage phone calls and do missing dose queue
67	The board doesn't seem to care about the quality of pharmacies. Seems like no changes have been made nor repercussions to retail pharmacies for understaffing pharmacies. It's a real issue and like it or not the board is our representing body.
68	try to have a limit on work load each pharmacist can do in a shift.
69	Universal use of barcoding within the hospital
70	Unsure. Staffing seems to be the glaring issue. Just numbers of pharmacist:patient doesnt accurately reflect the difficulty of the job or workload. Other things like dealing with residents, new nurses, etc also have a large impact on our ability to
71	We need to be more electronic based: emar, automated filling, ect
72	No response.

	A
1	**Question 56: What other recommendations for changes do you have that you believe would lead to improved patient care or patient safety?**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **c. Independent Pharmacy** **d. Department of Defense or Veterans Affairs Pharmacy** **e. Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)** **f. Consultant Pharmacist** **g. None of the above, I am currently unemployed or retired.** **No Response**
3	**Reponses**
4	1 to 4 tech ratio
5	1) if the board can mandate bathrooms for pharmacies surely, they can mandate uninterrupted lunch breaks too & supper breaks. 2) the board should really treat pharmacists a lot easier when they make mistakes. And the employer should be fined & punished much harsher than the pharmacist especially when you look at the working conditions, they make us work. A sliding scale of punishment for the employer should look at the staffing level, the PT, PTT, clerks, # of rx's/hour the pharmacist was working under, how many days straight they were working, whether they were under the weather at the time because they couldn't get relief, how many hours that week they worked and start sending the message to the employer that you treat pharmacist with respect & dignity in this state or you will be fined more & more. The way the courts have pre-sentencing report provided by P&P which looks at the totality of the circumstances in which the crime occurred & the background & history of the convicted, is how the board should be looking at the poor pharmacist & the greedy employer when something goes wrong with a stated goal of reducing the responsibility & punishment to the pharmacist & increasing it on his/her employer for setting up & creating the conditions in which this occurred. I see how the board treats pharmacists & there isn't much sympathy, caring or compassion for us. Gone are the days where a simple mistake is just that. Now the board goes after us for blood & money. Please chill out & treat us with a little pity & mercy for what we have to go through on a daily basis.
6	10 to 15 years ago, if our pharmacy was doing 3000 Rxs/week we would be allowed to have about 160+ hours of RPh/ week" when I left , we were allowed 98 " with the shift to put more of the workload on techs and computer advances that have helped effi
7	Adding patient safety ce for techs and Rph
8	Adequate rest time and uninterrupted meal periods o give time to unwind and rest, increased tech to pharmacist ratio
9	all electronic rx with insurance company interface to eliminate or greatly reduce non covered items
10	An extra pharmacist should be employed with overlapping shifts
11	Better pay
12	Don't have one at the moment
13	Eliminate mtm
14	Eliminating workplace metrics
15	fewer technicians per pharmacist
16	Get rid of performance metrics in retail settings.
17	Getting rid of the drive through option; that additional workflow adds unnecessary burden to the pharmacy staff.
18	Greater PBM regulation
19	Have a separate verification queue pre fill and post fill
20	Have more efficient work flow designs.
21	I have nothing but wonderful feedback regarding my current workplace. However, my previous workplace could use much improvement. I decided to leave it because of the unrealistic expectations they have on the pharmacy staff. Pre covid times were alrea
22	I struggle to keep competent, and well-trained pharmacy technicians in my pharmacy because pharmacies aren't getting reimbursed for the "dispensing" process of medications. Therefore, we are being forced to come up with non-dispensing opportunities to help pay for the technicians and pharmacy staff to do the job they were originally hired to perform.
23	If pharmacists were empowered to counsel all patients/care givers every time a prescription is dispensed. We would decrease errors and increase patient understanding and compliance, but this cannot be done when only one pharmacist is working.

	A
24	In general: chains delegate a certain amount of "tech hours" to their pharmacies based on the PREVIOUS year's amount of prescriptions SOLD (including vaccines). With chains always encouraging bringing in new patients, transfer-in's, and and pushing more vaccines every year, how can they think that providing the previous year's tech hours would suffice for THIS year? It's unfair not only to the employees but the patients as well. Many will wait days to get an antibiotic from an urgent care because these chains are so behind because they're only allocated a certain amount of tech or RPh hours. This is probably one of the worst things (in my opinion) that could have happened to pharmacy. Regional managers need to understand that they need to base their hours off the CURRENT need of the pharmacy - not just a "projected" need. ALSO... Pharmacy metrics (which most chains use) lead to massive amounts of anxiousness and when inadequately staffed lead to a decline in employees' mentality. I myself used to be so anxious in the pharmacy DUE TO METRICS and even was depressed at home thinking about the metrics we COULDN'T meet because WE WERE INADEQUATELY STAFFED, and even felt anxious before and arriving to my pharmacy because I knew we were behind in our day, ever single day.
25	Increase in pharmacists per shift
26	Increased staffing in general.
27	Increasing the number of pharmacist and not continually attempting to increase the number of technicians and technicians in training; for the benefit of for profit companies that lobby the board.
28	Just because a technician is certified does not mean that they can do the job. Personnel is unable to pick capable staff.
29	Less focus on metrics in retail pharmacies
30	Ltc - by fixing consulting hour to asnwer question
31	Making a pharmacist to prescription verification law, that factors both dispensing and non-dispensing duties. The law can have different ratios depending on the type of pharmacy and other workload factors (such as drive thru availability, number of pharmacy phone calls per day, etc.). Also, while eliminating non-dispensing duties for a pharmacist may free up time, sometimes performing those duties can help a pharmacist catch errors and improve patient care as well. Therefore, it would be great if a law could be implemented that focused more on increasing pharmacist staffing instead of focusing on eliminating a pharmacist's tasks. While increasing the number of non-pharmacist staff can help improve workflow, I only see that increasing drug errors since the pharmacist is the final check point.
32	Making sure all staff members have a sense of responsibility to the community they serve to provide the best pharmacy care possible & reminding them when standards are slipping, providing constructive advice to improve pharmacy care, and educate all staff to how important it is for accuracy to maintain the trust & confidence of the community they serve. What may appear as an unimportant detail to a staff member such as a wrong doctors name on a prescription label may alarm a patient because they think the medication in the bottle is for someone else, since they know they never saw the prescriber on the label.
33	Making sure that pharmacists get lunch and breaks regularly, and do not allow the big chains to avoid providing these basic needs
34	Measure patient care outcomes and overall wellness and safety
35	Monitor providers/physician poly pharmacy closely & not be afraid to question their rxs
36	MORE COUNSELING TIME
37	more pharmacist which will lead to less interruptions which leads to less errors
38	More scrutiny on retail chain to treat pharmacist and techs better
39	More staffing
40	More workforce
41	N/A
42	Na
43	NO drive thrus.
44	no metrics hanging over pharmacist and staff
45	No metrics. Totally trained technicians. Do not increase RPh / tech ratio
46	no suggestion
47	None
48	None at this time
49	None in present setting
50	Not applicable
51	Other states have transitioned into giving technicians more duties, such as the ability to check refills for prescriptions. Giving more responsibilities to technicians and having more technicians to help would free up the pharmacist to help in more clinical areas that are needed.
52	Our pharmacy dispensing system would greatly help patient care.
53	Pharmacist consults are important to me as this is my last check for patient safety and some pharmacists I worked with dont do the proper counseling

	A
54	pharmacists should be given the flexibility of their workday to ensure good communication with patients especially since their expertise as a healthcare provider is so valuable
55	Providing overlap pharmacist hours, increasing technician hours and technician ratio to allow the pharmacist to determine the pharmacy staffing needs to ensure safe dispensing practices.
56	Reduce inventory mgt by rph
57	Reduce work load for retail pharmacists
58	Remove the extreme level of micromanaging that exists. I cannot use my professional judgement to improve patient care because my job would be in danger if I chose to do something against employers policy
59	Removing metrics. Retail pharmacies put a lot of emphasis on meeting specific metrics within a timeframe and then get reprimanded for not meeting those metrics and in some cases are unattainable.
60	Separate pharmacist to handle phone calls and interruptions than the one responsible for checking outgoing Rx's. Computer systems that scan barcodes to enter inventory items and to check them as they leave.
61	Sexual education in the school system.
62	Staff that care about the job they perform.
63	target certain interactions between patients and pharmacist and pay a Pharmacist for completing these interactions
64	The adage of doing more with less has got to go. This cannot be what the world needs for proper, safe, effective patient care.
65	the retail chain pharmacists need more help.the pharmacists are over worked. there should be 2 pharmasists on each shift.
66	There should be more pharmacists in retail establishments. The work should not be primarily performed by technicians.
67	Treat human beings with respect. Eliminate non-stop alerts to handle more calls. Alert fatigue is real.
68	Try to complete task before they are due to reduce having to rush to finish work.
69	Unfortunately, we cannot safely multi task. Pharmacists should be assigned a task and then rotate but when I was in retail I was expected to do vaccines, fills, answer calls, pt consults, customer questions, drive thru, communicate with other prescribers, pharmacies, insurance.
70	Walgreens needs to remove metrics. Data verification under 12 seconds and clinical review under 5 seconds is a safety risk to Pt.
71	We could use more space in out dispensing area
72	We need more pharmacist to assist with the work load so we can safely dispense the medications for patients. With added pharmacist during the day can also increase technician staffing. We should have clinics days where we can provide vaccinations and pharmacist can alternate between filling and complete vaccinations at the same time. Large corporations are closing down retail pharmacies and decreasing staff levels so they have more profitability. We need to do better to have more pharmacist during the day (even mid shift) so that we can service our patients more effectively and safely
73	While we are human more staff in general that can have built in safety check processes would reduce patient safety errors.
74	No response.

	A
1	**Question 57: Please share any other comments you may have:**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **b. Retail Chain Pharmacy**
3	**Responses**
4	15 breaks for rph in addition to 30 min lunch when working 10 or more hrs
5	30 minute lunch never is 30 minutes. We always close late and its more of a time to catch up.
6	A direct line of anonymous tips/complaints for pharmacists regarding employers could be helpful. Unfortunately the threat of retaliation and termination does not allow pharmacists/technicians to express their concerns in the current environment.
7	Add one 15 minute break on top of the lunch break which is 30 mins. When I work for 13 hours, starting from 8am, and take a lunch at 1:30-2pm, and it gets busier at 4-7pm.. pharmacist should be allowed a 15 min break in the evening just to breathe, use t
8	Adequate staffing and pay for all pharmacy employees
9	All pharmacies in NV (not only new ones or freshly renovated ones) should have a private bathroom for Pharmacy staff; this would decrease the diversion of drugs, and prolonged unnecessary breaks by PTs, and most of all, it would dignify the Pharmacy Staff, because at pharmacies without bathrooms, Pharmacist and Technicians alike have to use public restrooms that are often unsanitary, with biological hazards such as urine, feces, diapers, and even used hypodermic needles throughout the restroom.
10	Also, pharmacists are given so many responsibilities and are given little leeway to delegate these to other properly trained staff. Doctors and other clinicians are trusted to delegate many of their tasks, yet pharmacists are not treated the same. In a
11	Always have 2 pharmacists on a busy day
12	as a floater, I have witnessed there were many toxic work environments in every store location, low moral, not treating each other as humans, high employee turnaround, lack of training staff
13	Background checks need to be efficient, not taking a month to process.
14	Better training for new grad pharmacists. Disappointed with the amount of follow-up training is required for next gen pharmacists.
15	changing the required number of technicians and pharmacist required to fill a certain # of scripts per day / time frame, would be a big help. I see 2 options that would help with pharmacy to patient safety issues. 1. if pharmacist were to unionize across the state or 2 if the state were to put in restrictions to help. unfortunately, I think it is the nature of large corporations to push for every possibility of increased margins regardless of patient safely and more importantly employee safety. I sincerely hope the state is helpful to not only the public but the people who serve them in this capacity.
16	Companies are putting a lot of pressure to pharmacist on increasing prescription and vaccines and testing and this only going to get worst on patients safety
17	Competitive pay minimum $60 or more per hour We are salary and sometimes have to come in early or leave late to finish job Not every shift gets a lunch break every day No chairs available
18	Corporate metrics as a priory instead of patient safety should stop
19	Corporate pharmacy is only about the dollar. Making them money to facilitate their bonuses. We need to take it back and focus on whats important and thats building patient relationships and safety. Why do we have to rush and move them along like c
20	[redacted], [redacted], [redacted] want to increase Technicians but the issue is we need more pharmacist staffing.
21	Drs are the cause of drug abuse. They are the ones prescribing the drugs of abuse.
22	During busy hours we need additional cashier/s but often do not have it or front store is unable to provide. To have additional staff for busy hours such as from 11-30-1 pm and 4-6 pm.
23	efficient workload and safety working environment
24	Eliminate metric based practice and let us focus on providing quality and safe patient practice and interaction
25	Employer does not care about patient safety. They only want you to do more with less help.

	A
26	Every single year corporate cuts our hours to bare minimum in the summer saying because the pharmacy is slower in summer However, this year with Covid making a comeback, Covid testing for travel and school starting at the beginning of August, there is no summer slowdown. We suffer through it, then once we get flu vaccines in we get hours restored. This year of course though, the new Covid vaccine (Omicron variant) came out at the same time as the new RSV vaccine along with the seasonal Flu vaccine. So now this year it was a triple whammy. Many people were getting all three at the same time. This is terrific for the public, but a difficult challenge for pharmacies, since instead of just flu vaccines we are the main source for the public to get vaccinated. We also do other vaccines so our work load pre-school starting is extremely high due to school vaccines. Then as soon as school starts, the kids get sick and then the whole family is on antibiotics, steroids, cough medicine and albuterol inhalers. These days pharmacies are a lab, an immunization center, a MTM hub, a training center for new diabetes patients, a walk in medical advice hub, a place where you can get your blood pressure checked for free-so you can send your results in to the Tele-doc, as well as doing more prescriptions than ever. Today I had to apologize to an elderly lady at least 7 times because she had to sit in the waiting room for a while to get a vaccine. I was trained to do all of this, but I can not do it all at the same time, as well as giving good counsel on prescriptions, and verifying them accurately and be polite, kind courteous, helpful and be in a good mood as I am expected to be.
27	Everyone I work with feels burned out all the time. And we have more staff then some of the other chains- it's the fast pace environment and increase in additional duties (vaccinations, BCP prescribing, etc) and LONG daily and weekly hours that is causing this.
28	Front end management shouldn't try to pressure pharmacists to fill narcotic rx just to meet script volume demands.
29	Give employees incentives. Stop asking for more without appreciating what we are already doing
30	Give us a one or two page summary of the changes to pharmacy law each year.
31	Hard to find technicians and cashiers who will stay longer.
32	Have 2 rph on duty or 1 rph and intern to help with counseling and managing techs
33	have one pharmacist or tech be in charge of all calls and vaccines
34	Have the rest period longer than 30 minutes. Have enough staff to answer the phones, give immunizations, put away drugs on truck delivery days.
35	Have to get rid of the metrics , Very high goals and increase labor help . Must have mandatory so many hours of help for said amount of prescriptions, Vaccines and MTM and other Clinical Engagements.
36	Having pharmacy technicians required to be able to give vaccines would greatly help with workflow. When there is a high demand for vaccines it is difficult for me to do all the vaccines , counsel, answer doctor phone calls and check on medications for pa
37	How long does it take to fill one prescription?
38	I actually quit the retail job because of safety. I felt safety is definitely not built into the system and the flow. I don't want to hurt someone unintentionally from work so I had to quit. I want to be able to go to sleep everyday because I don't know what I would do if a wrong dispensing causes great harm or death to a patient.
39	I am concerned about the current corporate focus on PROFITS over PATIENT CARE!! [redacted] IS REPORTING RECORD PROFITS WHILE CUTTING PHARMAIST'S AND TECHNICIAN'S HOURS.
40	I am just filling this as a pharmacist who worked for [redacted] for two years and quit in july,2023 becuase of horrible work conditions. I am doing this in support of my colleagues who work at a chain pharmacy
41	I am personally disappointed with my employer. Today for example was ridiculous. The other pharmacist called in sick, thus making me do the work of 2 pharmacists. I asked scheduler for help she said there is none available. I told her that the pharmacist to tech ratio was off, she told me to send them home.
42	I and my coworkers have been sick often due to unsafe work conditions. We have complained about space issues, tripping over mats/totes/trash bins, and not having clean air vents (filters have not been changed in the 9 years I've worked at my location). Supervisors are told and all they want to do is add another computer here or there to process more orders.
43	I appreciate that the NV board of pharmacy has sent out a survey to evaluate the current sentiments of working pharmacists in the state.
44	I believe there should be a heavier fine for pharmacies that break the law. The $5,000 or $10,000 fines are nothing to these companies that make 20 billion dollars a year in profit. California and Illinois hits pharmacies with heavier fines. I just believe that would help these companies get the memo and make changes for the better.
45	I can see why the world of pharmacy is not a favorable career as before as 15 years ago. Too much student loans, with less pay, and its a high stressful job!
46	I do not support increasing pharmacist to tech ratio, I think it adds risk to my license.
47	I don't feel safe working in retail. The patients should definitely not feel safe either.
48	I enjoy the people I work with Techs and rph work as a team [redacted] was the worst employer I worked for with regards to not being allowed a lunch break and disregarding patient safety
49	I feel All pharmacists should punch a clock. As a previous PIC, I worked an immense number of hours over my scheduled workshift for non dispensing task, paperwork & trying to catch up.

	A
50	I feel that if we have a hard time staffing or finding hires, district leaders and corporate leaders should greatly reduce our metrics or goals. District managers often tell us that the only way we can get more staffing œhours for our store is to sell
51	I feel that patient safety has been put on the back burner and all that is the focus is profits. I refuse to come in early, stay later, or close late and open at regular time for lunch (cutting out 30 min short) especially without pay or proper staffing.
52	I feel unsafe operating a pharmacy by myself without a technician staffed
53	I feel very burnt out and its very sad that it has come to this. If I could I would change my profession. I dont recommend anyone becoming a pharmacist anymore. Its just too much pressure for us to handle. I have had to start antidepressants to get
54	I feel, in recent months, especially with some brave colleagues threatening to walk off the job, things are slowly beginning to improve, but after 10+ years I have never been able to wonder why State Boards and professional pharmacy organizations (APhA)
55	I genuinely believe that the Board of Pharmacy has a responsibility to address these concerns and advocate for standards that prioritize patient safety over productivity goals. Your attention to this matter is crucial in maintaining the integrity of pharmaceutical care and, ultimately, safeguarding the well-being of those we serve. Additionally, I urge the Board to consider the importance of fostering safe work environments for pharmacy staff. The current high-pressure conditions, characterized by unrealistic timeframes for prescription reviews and drug utilization assessments, contribute to a stressful workplace that is mentally draining for pharmacists and support staff alike. Addressing these concerns is not only essential for patient safety but also integral to ensuring the overall health and well-being of the pharmacy workforce.
56	I graduated in 2014. At that time my preceptor, a full professor and chair of the residency program, told me that she left a major retail chain long ago (for her) because a good day was being able to get the correct drug to the correct patient. I relish the opportunities I have to touch a patient's life and treat them like a real patient and not just a script number. But those days are so few and far between while I'm working at a major chain. It's disgusting. I love being a retail pharmacist. It is my calling. I left my first career to become a retail pharmacist. I don't want to regret that decision.
57	i have answered this survey based on my previous employer that i have recently just left 3 months ago. i had stayed with this certain 3 letter chain pharmacy company for about 14 years and was given so much responsibilities with no compensation (ie. raises for 5 years or no acknowledgement of appreciation).. just more work, with the same amount of pay. the turnover of pharmacy technicians were very high because either the company was desperate for help and all these new people did not even go to pharmacy tech school because it became no longer a "requirement" to be a pharmacy technician. we were just hiring people who was willing to work and learn pharmacy. i think thats where BOP's requirements of becoming a technician failed. if an rph have to go to school and learn the foundation of pharmacy, there should be a requirement for technicians to at least learn BASIC pharmacy (ie. sig codes, brand and generic meds, calculations) knowledge. i felt as an rph i was teaching a pharmacy tech how to do pharmacy, instead of checking the accuracy of prescriptions. since i have left that employer and joined another pharmacy that does way more prescriptions with less non-dispensing duties and no metrics to go by, i have felt more at ease and less stressed. the new employer has equipped us pharmacists with better high performing technicians.
58	I hope something changes for the better & SOON. The profession of pharmacy has become a shame over the years. I really hope the board is going to do something that will make a difference & not just slap some lipstick on a pig. Talk is cheap.
59	I need to contact you because my retail chain of 25 years recently terminated me due to not doing enough metrics (even though I was).
60	I recently stepped down from management after 15 years. My answers today are somewhat different than when I was managing earlier this year. My experience and views on how to deal with customers and staff have changed over the years and it has made our jobs in retail more difficult on many different levels. I still love pharmacy and will continue to work as a pharmacist but yes something must be done to make the workplace better for everyone.
61	I think increased staffing would fix almost all the problems. I also believe insurances contracting with certain pharmacies leads to a decrease in patient care. I know patients who want to leave a pharmacy but cant because of insurance preferences and her budget
62	I think our staffing hours should not be based on unattainable scorecards. a cut in man hours lengthens time for pts to get med at right time

	A
63	I think people forget that we are clinicians, not money makers. We have no degree in business. We have a doctorate and a license to dispense. Someone with a bachelors degree and no dispensing license should not have a say in what I do in the pharmacy and should not push any numbers on me. No one with just a high school diploma who is a store manager should be my boss. I don't mean for this to sound condescending. I worked hard for my degree. I want the best for my patients. This is why I went to school. I do not understand how a store manager can have any say about the pharmacy. I do not understand how a district manager can have no pharmacy background but also have a say in my pharmacy. If you are going to be higher up in a corporate retail chain, it should be required for you to have a PharmD or equivalent because they make decisions that are not best for patients but are best for business because they are not clinicians. They should not be able to hold policies and business models over any pharmacist because it is our license that we are using. It is up to us whether we dispense a medication or not and to use our best judgement. If a district manager wants to run a pharmacy a certain way, they can use their dispensing license to do so.
64	I used to work 10 hours a day, but now it is only 8 hours, so much better
65	I will never work retail pharmacy again. Big chain companies care only about the bottom line. I developed anxiety because every day I went to work, I was afraid I was going to harm a patient. I was so overworked, under staffed and spent countless hours working off the clock just to finish my daily work. Retail pharmacy has turned into fast food mentality. There is zero respect for our profession from customers and other health care professionals. Its incredibly sad.
66	I wish I had known what I was getting myself into early on before accumulating hundreds of thousands in debt for education and be forced to work
67	I work consistently 4 or even 7 hours extra for free, on top of my regular 12 hours day shift. Without a slip of water or food or restroom break for those paid 12 hours shift. I cannot keep giving my free time to the company that has priority for profit over patient. Please help the pharmacy professionals. We are so helpless. Please.
68	I work in a high volume retail pharmacy. The processing and filling of prescriptions is essentially like playing an intense video game. For those who understand that, imagine someone constantly chatting in your ear, 5 phone lines ringing, and you need to leave your computer frequently. How successful was your game?
69	I would like 4 tech ratio to accomplish and delegate tasks to increase patient related needs and requests. Also volume related staffing of rphs and supportive personnel. I have been given what I need but I would like more to provide even better care and service for my patients
70	I would like to express my deep concerns regarding the current state of retail chain pharmacy, particularly the impact of corporate practices on staff well-being and patient safety. A significant change is urgently needed in the retail pharmacy sector. The relentless pursuit of profits by corporations is not only detrimental to the health and well-being of the pharmacy staff but also poses a serious risk to patient safety. The intense pressure to meet corporate expectations often leads to a work environment where pharmacists and technicians are stretched to their limits. This situation is not sustainable and is counterproductive to the primary goal of any healthcare profession: ensuring the safety and well-being of patients. The well-being of staff in retail pharmacies should be a top priority. When pharmacists and their teams are adequately supported and have the necessary resources, they are in a better position to provide high-quality care. This includes ensuring reasonable workloads, fair compensation, adequate rest periods, and a supportive work environment, eliminating metrics. By shifting the focus towards taking care of pharmacists and pharmacy technicians, we can create a more positive and productive work environment. This change will not only improve the morale and job satisfaction of the pharmacy staff but will also lead to better patient outcomes. In conclusion, I urge the board to consider the serious implications of the current corporate practices in retail pharmacies. It is imperative to recognize that prioritizing the well-being of pharmacy staff will ultimately lead to improved patient safety and care. A reevaluation of these practices and a commitment to positive change are essential for the future of the pharmacy profession and the health of the communities we serve. I remain dedicated to upholding the oath I took as a pharmacist, prioritizing patient care and safety above all else.
71	I would like to see the NVBOP try and have at least an annual paid high end dinner drinks maybe a well know guest speaker and live band at a decent casino in Vegas. You could even put an optional $100 entry fee for those that wanted to attend when we get licensed every 2 yrs. Pharmacist are hermits mostly and could really use a push in a group organization direction like the AMA .
72	Ive been a pharmacist for 11 years and Im deeply saddened with how retail pharmacy has fallen to these big corporations. I truly hope that nevada law can make the necessary changes to help better protect our patients and pharmacists. Its been a lo
73	Ive only been a pharmacist for 3 years, but Ive changed employment settings 5 times and at all 5 locations, we arent properly staffed. Employers do not care about us and we are constantly undermined and under appreciated. There are so many days wh
74	If I had a skill set that would translate into an income within the same realm of a pharmacist I would have left pharmacy already. However, my skillset is specialized and cannot easily lead into another career path. I have stayed with my company only because I do not want to work for either of the leaders of our industry known as [redacted] and [redacted]. It is my understanding that it is a couple horror show working for them. I was also told during a board visit that at least I do not work for one of them and that the groceries stores were much better.

	A
75	if you have more techs it just adds to the pharmacist having to monitor, check, review, and answer questions.
76	I'm not sure how to fix things, but pharmacy does not appear to be moving in a positive direction for patients or pharmacists or technicians.
77	Immunizations and other non dispensing administrations should be done at times that do not slow or disrupt normal pharmacy dispensing duties
78	In closing, pharmacist base salary and 40K benefits need to be addressed, so that the best Pharmacists can be hired.
79	In the retail setting we have selling, filling, and other services. Let's be clear that adequate staffing should be on entering not sold status.
80	Increase rate of pay
81	Increasing non-pharmacist staff in the pharmacy can actually increase the burden on the pharmacist on duty to provide proper supervision.
82	Increasing staff would greatly help with providing the best patient care so you have time to actually focus on each prescription/patient that comes in without feeling rushed or stressed. There were numerous times I was told I take too long with one patie
83	increasing tech hours at bigger retain chains especially during the winter season and having a second pharmacist on helps with work load and allows for better patient care. patient and pharmacy won't feel rush or stress to meet certain criterias
84	Interruptions effect my accuracy the most.
85	It appears the developers of this survey do not or have not worked in the "trenches" of our profession.
86	It is extremely difficult to find and hire competent cashiers and technicians. The job is very stressful and the pay doesnt encourage qualified and dedicated applicants.
87	It was impossible to get to know my patients medical needs and truly take care of them like pharmacists should. Proper counseling hardly ever happened. Patients and patient safety need to take priority over company profits.
88	It wasn't until I left chain retail that I realized how negative work had made me. After some time away, I no longer believe the worst in everybody and instead believe there is good in people again. I feel like the "public" needs changing. Not just staffing, metrics, etc. And I don't know how to do that.
89	Its a tough work not easy at all but job opportunity for RpH now is very limited so far I dont see any job for me but retail
90	Let pharmacist and technicians focus on filling medications correctly. Phone calls for mtms, delayed picked up should have dedicated additional staff focusing on these tasks as opposed to doing multiple task in verifying prescriptions and doing calls causing increase in error incident.
91	Many pharmacists are burnt out which is leading to a decrease in productivity which then increases the workload for other pharmacists. This creates a viscous, exhausting, cycle of burnout.
92	Miss you guys ;)
93	More adequate RPh and techs and clerks help
94	More help
95	More inspections, questions and requirements on the companies and their metrics/requirements themselves, rather than just the physical pharmacies and their PIC's alone. Corporations should have to answer more directly to the BOP in each state they're operating pharmacies in, considering they set the expectations and requirements on the pharmacists themselves at the threat of job loss/wage loss/bonus loss/etc if those expectations aren't met, no matter how dangerous those working conditions are to the patients and employees themselves.
96	More pharmacists and technicians hours during any given shift, increase pay for our hard working technicians so the experienced technician will stay with us
97	More power to the pharmacist to decide staffing needs, not the company, less money going to corporations and more staying in the community
98	More staffing to help patient care and not rushing. Also better working environment for trainees.
99	More technicians would provide a safer and more calm environment, allowing them to time to focus and not make errors. When our technicians make errors it affects the patient and the pharmacist has to spend time correcting the issues. The technicians face a lot of pressure and are often interrupted too
100	Most employers today use black and white method of using numbers/ metrics to schedule staffs without realizing that pharmacists today have to take on so many non-dispensing services. And that leads to short staffs. Employers always push to improve customer service while trimming down hours.
101	My employer requires us to work 9.5 hrs a day 5 days a week. This in my opinion leads to burnout and an imbalanced work/life balance. No flexibility to work longer hours and have more days off. This would GREATLY improve work satisfaction and less burnout having that option.
102	My priority is always patient safety and care over the number of prescriptions I verify, but as a conscientious employee I cant help but feel stressed at the pharmacist work load.

	A
103	My store is probably one of the better staffed stores, but it wasn't always like that. We've recently been given more hours for staffing, but that was only after issues arose from the increased demand in vaccines/scripts. While we are in a safer position now than other pharmacies, we haven't always been there, and it won't always be like that. And while I don't work as many extra hours now as others, it's because I've given up. I've worked 14 hours days when it was supposed to be only 11 to get all my tasks caught up. I could easily do that now, but I choose to not let work run my life. Just because I don't, doesn't mean that I couldn't, or shouldn't.
104	N
105	N/A
106	NA
107	Needs rule by state like California to increase safety
108	Nevada require much more counseling log than other states that require interrupt pharmacist work too frequently
109	New companies are remotely staffing multiple hospital pharmacies and have already reached levels that rival retail chain pharmacy workloads. I would suggest this be the next area of concern after making sure retail chain pharmacies are appropriately staffed and structured to avoid obvious breaks in the chain of public and patient safety for testing, vaccinations and dispensing.
110	Next thing you know the chains will want to get rid of pharmacists in the pharmacy and have all the checks done remotely or by AI. This profession used to be so great. Why has pharmacy leadership allowed all of this to happen? Plus how can you say this s
111	no comment
112	Non
113	Non Pharmacists (non licensed) personnel should not be allowed to override decisions made by licensed pharmacists regarding the safe operation of the pharmacy at any time.
114	None
115	None at this time.
116	Not having to worry about non-patient/dispensing tasks will improve patient safety.
117	One of the biggest current problems is dealing with the abuse and general time consumption of dealing with drug shortages.
118	Opioid crisis is out of control. We as pharmacists need help in this area.
119	Our industry is evolving rapidly. Especially with fulfillment methods, most of our chains are trying to ease the burden of the balance of dispensing vs nondispensing activities with microfilfillment which is not yet a well oiled machine just yet but at least is being addressed proactively. I really feel the best possible support is anti-PBM legislation and make Nevada open access and drug price transparency.
120	Our profession has become very undesirable leaving high turn over rates of underpaid/overworked techs and testament to our local pharmacy program enrolling "70% less" pharmD candidates than usual. We feel defeated everyday on duty due to understaffing to support the demands of our community safely and efficiently. I see the trend of people leaving the profession due to frustration causing more stress on those who stay. And the last 3 years the ones who stayed are slowly leaving. This cycle is causing unsafe/inefficient patient care across the nation. Please please please help our profession.
121	Our retail chain recently implemented 30 minutes pharmacy lunch break. Due to the workload, I use this time to catch-up because the phones are off and the gates are closed at the pharmacy. I've only actually eaten twice since they started our 30 minute meal break few months ago.
122	Outline the quantity and MME that can be prescribed exclusively for dental purposes and migraines. A lot of patients that take narcotics for chronic pain are using them for migraines. Legislate that post surgical pain prescriptions should be sent to the pharmacy only post surgery. I see people send in and fill prescriptions for post surgical pain management 2-4 weeks before surgery. Some of the surgery might never happen and how do you determine how much medicine to prescribe for a surgery you did not perform?
123	Patient safety is number one priority for me and adding extra tasks all this non medication services CLIA services affecting pharmacist to focus on medication therapy and its increase stress and work load which affect patient safety
124	Patients do not respect pharmacist anymore the amount of verbal abuse, license threatening and corporate threatening in a retail setting is unacceptable. Corporate surveys for patient œretention should be eliminated. Retention is not based on servic
125	Pay the technicians and pharmacist well enough to boost their morale and motivation.
126	People and Patient driven instead of metrics.. Focus on right behaviors and forget metrics completely..
127	People generally and understandably, do not want to wait. Metrics focused on prescriptions but does not count, as this survey has put it, non-dispensing services, phones, customer/patients and other variables does not make sense. I understand metrics, why there is one but not including everything makes it an unfair measure of practice. Customer surveys, metrics, non-dispensing services are all factors, among others, in pharmacy practice now.
128	Pharmaceutical technicians should not give consultation or suggestions to patients just because the pharmacist is too busy attending to non-dispensing services

	A
129	Pharmacies should be required to access Webiz before administering vaccines. Too many times I have seen unnecessary or duplicate vaccines administered.
130	Pharmacists are valuable - stop replacing pharmacists with techs - fight for the profession for adequate reimbursement that allows more than 1 pharmacist serving the public
131	Pharmacists need to be union and have someone protecting their rights. Unfortunately, all the bad practice and illegality is well known by Nevada Bord but they really Do Not Care!
132	Pharmacists should be allowed to sit down. We are not robots . We deserve to sit . Some times we are so pressed we dont even use the bathroom for ours . Fearful that a patient maybe upset waiting for the pharmacist for consultation
133	Pharmacy corporations should not be allowed to pressure pharmacist to verify prescriptions by promised time it is a unnecessary metric, when caring for the patient is more important
134	Pharmacy has become a rat race from the time the pharmacy opens until it closes...it has become a race to finish and fill as many prescriptions as possible. Drive thru services made it like fast food instead of safety. Maybe if there were more pharmacies so all the work wasn't all in one place. More pharmacist working at a time.
135	Pharmacy insurance or discount coupons from manufacturers should be made available to participating pharmacies prior to drop off or pick up to avoid any delay.
136	Pharmacy run score card to compare the all the store every week, Performance measure or time takes for each stage. 56 Seconds to verify? How many mtm ? Vaccination, per week , compare all store increases every week , comparing increases stress, anxiety if you behind then others. ,since all store has different thing to deal .comparison does not help rather than increase stress The time set up by System is very unrealistic ,put pharmacist in rush that cause errors
137	PHARMACY SUPERVISORS AND MANAGEMENT SHOULD NOT BE IN PLACE TO DRIVE PHARMACY PROFITS THROUGH DRIVING METRICS. THEY USED TO BE THERE FOR ACTUAL SUPPORT.
138	Pharmacy Technicians should get salary increase specially if they can help with immunization.
139	Please enforce my mandatory 30 minute break.
140	Please make a legal requirement for each pharmacy to operate safely with at least 2 to 3 technician minimum per 1 pharmacist so that the employer would not cut too many hours leaving us having a few hours of tech per day, 10 hour shift. Due to low number of tech hours budget weekly, we do not have enough number of technicians to assist all customers.
141	Please read through topic discussions on www.reddit.com/r/pharmacy and www.reddit.com/r/pharmacist
142	Please require pharmacies staff 2 pharmacists per shift.
143	Prescribers are difficult to reach when verifying prescriptions. Medical assistants have become an obstacle that impairs the efficient verification of prescriptions.
144	Proper compensation would be nice to avoid burnout of technicians and Pharmacists, though this appears to be an issue with corporate and their stance where patient safety matters only when it doesn't affect their profits.
145	Proper workload balance
146	Pushed too hard to reach unattainable metric/goals and told its all to keep patients healthy when its most about profits. Too much to constantly keep up with as a PIC: Compliance audits/inspections, metrics, BOP inspections, inventory, excessive amounts
147	Really hope the Board of Pharmacy is able to do something about current work conditions as it not only affects the employees but patients. I have been a pharmacist for 25 years and it has been great in the beginning but has become a multi-tasking nightmare. Companies are only looking at the profit and # of patients that can be processed. Not processed safely. If something happens then it is the pharmacist's fault as they shouldn't have rushed.... but they have to in order to hit the "goals". I am actively pursuing goals to get out of the profession that I used to love.
148	Regarding the idea of increasing the number of technicians a pharmacist can supervise, I believe it could suffer from diminishing returns. Time that could be spent doing clinical tasks, such as consultation and communicating with other healthcare providers, may be used to supervise additional staff instead. I don't believe this is where the role of a pharmacist should be going.
149	Respect for pharmacist, some management treat them like a home servant
150	Retail pharmacy has become unbearable. I've left a large chain because of the impossible expectations.
151	Retail pharmacy makes one feel as if they are on the brink of capsizing on a sinking boat. More pharmacists are required to solve issues regarding patient safety (consultations) and all non pharmacy related services like immunizations.
152	Retail Rphs are overworked and under paid. Performance evaluations are just ridiculous and unfair. Even if your manager gave you a good review but the other people involved in giving a raise will mandatory lower your score or since youve been in the c
153	Salaried pharmacists should have overtime pay too since a lot of us stay behind after our shift just to clear it up for the people working the next day. Or just have two pharmacists scheduled in a day so theres no work left behind after shifts.
154	Should be a regulation for the chain pharmacies to always have technician on duty. Im considering going to the state legislature about this concern.

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155	Should pay for pharmacist work after hours. Should have all electronic prescriptions, no more handwritten prescriptions. Hand written prescriptions are not safe most of the time.
156	Since COVID I have struggled with mental health and work continues to expect more and more without taking anything off the plate. They say they are helping but they arent. They budget for a skeleton crew at all times and expect you to constantly do the
157	Technicians need to make more than a gas station attendee
158	Technicians should be required to do all vaccinations.
159	Thank you for addressing this issue!
160	Thank you for doing this.
161	Thank you for sending out this survey and listening to our concerns.
162	Thank you from the bottom of my heart for this survey. The questions asked here have been well thought-out and inquired about a variety of topics.
163	Thank you NV BOP for this initiative! I hope there would be changes implemented after this survey as soon as possible. The demands and responsibilities for pharmacists are always increasing. While I am happy to do extra tasks to help serve our patients, additional help is needed from the company and government to ensure the patient's care and safety. I feel that the laws and policies are not fast enough to adapt to the changing landscape of the pharmacy practice. Increase communication from the BOP to pharmacy staff and public would be beneficial; consistent monthly newsletters would be nice; regular open dialogues or public forums would be favorable.
164	Thank you so much for doing this. It really feels good to feel like someone is listening, after feeling like we dont matter. My first job was at a Taco Bell when I was young. I hated it, and determined to never work there again. Pharmacy has become
165	The board of pharmacy needs to protect retail community chain pharmacists unsafe workplace conditions to improve patient safety. In Nevada, community chain pharmacists need to be required to staff the pharmacies to complete workflow daily.
166	The board of pharmacy was slow to implement laws and care about pharmacist to help and prevent errors.
167	The BOP should care more and investigate when a pharmacist files a complaint about working conditions in a pharmacy. The way a company runs its businesses has a direct effect on patient safety. It is discouraging to be told that BOP cannot do anything for us when patient safety is on the line. Our patients deserve better.
168	The disrespect and hostility for doing our job should not be tolerated
169	The metric system and management style mainly contributed the ability to verify the prescription effectively and safely for the patients. In addition, the pharmacy manager puts more pressure on pharmacy staff for the bonus payment, which even puts more burden on the pharmacists to promote patient safety. Therefore, I would recommend the Board of Pharmacy set a guideline for a certain number of prescriptions for pharmacists to verify per day or week. In addition, pharmacists must have enough time to verify and check the prescriptions in the best condition. If any pharmacy manager takes advantage of his or her power to pressure his or her staff to verify faster and provide unsafe working conditions. Please have a phone number or specific forms for the staff pharmacists to express their concerns and present complaints to the Board of Pharmacy about the management. Thank you,
170	The metrics is super stressful
171	The primary practice setting that I listed was with [redacted] retail pharmacy (my previous employer). There were days and weeks when I could not relax even on my days off. I would come to work anxious about the workload and metrics that my employer demanded from us, dealing with multiple situations unprepared by my employer, and constantly worrying whether or not, my mental health is more important than the company's values. Due to my large workload and multiple tasks at the pharmacy, I felt like it was easy to make a medication error, which led to increased stress levels and anxiety at work. My healthcare physicians suggested I quit my job due to poor work conditions at my retail pharmacy company, which led to taking medications for anxiety, depression, and eczema flares due to work stress. I have floated to several different [redacted] locations and the work conditions are the same or worse with less pharmacy support.
172	The safe number per day really depends on the system. At [redacted] you can safely fill more because their computer system is designed to prevent medication errors. Other places, not so much.
173	The solution is simple, but many BoPs refuse to act. Require big companies to ensure adequate help isnt asking a lot when you are dealing with patient safety. Just ask the this question to any other medical professionals: Have you EVER seen another whi
174	The workload that has been put on us is unfair and unsafe on top of tech hours being cut so badly we are working by ourselves. Pharmacy never used to be like this. We have lost so many great techs because of cut hours/wages and lost great pharmacists due

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175	There are not enough labor laws to help protect labor rights of pharmacists in Nevada. Salaried pharmacists are expected to complete work/hours outside of work in addition to scheduled pharmacy hours without pay. Pay increases even for the highest performers have barely made it to 2-3% yearly increase which to is not enough to help offset inflation. New graduates or pharmacists changing companies are offered $50-60 hourly with many given less than 25 hours weekly. It is disappointing this is the same offer from 15-20 years ago with significantly more competition entering the workforce, despite school tuition hikes in the last decade. The working conditions, minimal labor protection, and no incentive in pay guarantee to offset the expenses/commitment has plummeted interest in the profession, as seen in the lack of applicants in the pharmacy school. Great candidates are looking into other professions, and sadly pharmacists are discouraging their own family and friends from our profession due to the bleak job outlook and poor working conditions. Our community needs good pharmacists to guarantee their medication safety, and a lot needs to be changed to regain a positive interest in our profession. Our neighboring state California has taken strides in the profession, gaining workforce rights like requiring pharmacists to clock in and out during working hours and during lunch to protect from interruptions so they are adequately paid for their time. They are not allowed to open the pharmacy without a technician present. The Board no longer allows companies to use business metrics and goals to be evaluated because it affects patient safety. The bottom line is that this the safest process that we can do to ensure errors are kept minimal without interruptions and the stress of meeting metrics so that pharmacist can fully focus on preventing errors and identifying safety issues. I truly believe that not allowing quantitative measurements that pharmacists stress to add in addition to dispensing and requiring at least minimal technician hours (not more technicians allowable) will vastly decrease the number of errors and patients hurt so we do not compromise their care.
176	There should always be at least 1 technician working with a pharmacist at all times (like in California) to promote patient safety and safety in the workplace. Its scary to work by yourself in the pharmacy. Sometimes we get a last minute rush, or a fam
177	There should be a Pharmacist assign for MTM and equip so less interuptions in filling, dispensing and verification of Prescription.
178	They do not have hours for sick call. I think mental health is extremely important for pharmacists as well. All pharmacists need mental health breaks
179	Things need to change!! We have to stop big retail chains dictate what we do without regard to patient safety.
180	This is not the same profession that I began 28 years ago. Had I known it would become what it is, I never would have become a pharmacist
181	This survey failed to address the pharmacy profession other than retail. Expectaion to fill Rx's as quickly as possible puts patient safety at risk. For example, I would like to know how patient safety is paramount when doing clinical review and one is only given 6 seconds to perform a proper review.
182	Transfer of prescription must be limited, or needs to go back to the old way of limiting rx to be transferred only if rx has filled at least once in the pharmacy. If Md send rx to wrong pharmacy, they need to resend to the right pharmacy instead having pharmacy to transfer for their mistake.
183	Travel vaccines/meds consultations and immunizations have taken out a lot of time from our work flow. Then we still have to clear the queues for that day. We have to follow companys protocols to accept or deny new patients but sometimes feeling the com
184	Twelve hour shifts with one thirty-minute lunch break are ridiculous. Also, expecting one pharmacist to deal with dispensing prescriptions, vaccines, patient consults, answer customer questions, handle drive-thu issues, ring register, deal with inventory and ordering and everything else we do with no errors is insane. I'm old enough and experienced enough to say "no" if necessary but most pharmacists won't and errors will become more common and more serious it the current situation continues.
185	Ultimately the safety of the patients is our number one priority and secondly the pharmacist and technicians well being & mental sanity need to be addressed due to unrealistic expectations and pressure from the companies metrics! The outrageous workl
186	Unrelated to the board, but the pay scale for pharmacy is also not very good for chain retail pharmacies, which exacerbates staffing issues.
187	Unsafe to voice concerns without feeling that I put my job at risk.
188	Until ALL interruptions are eliminated or decreased and third party is reformed or eliminated, NOTHING will change or improve
189	[redacted] caused me to have psychological damage from the stress, weight gain, lack of rest periods (because of no overlap) lack of bathroom breaks and constantly being berated by patients with no repercussions from corporate when my life was threatened on multiple accounts
190	[redacted]
191	[redacted] greed is excessive . Managers and technicians are incentivized to pushing vaccines
192	[redacted] in Las Vegas is the employer referred to above

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193	We get a designated lunch, but no additional rest periods for pharmacists, only technicians get breaks. Employees don't have enough vacation/sick time to take well-deserved breaks and take time off when sick, and we don't have any coverage when we do need time off, which leads to people working when sick, injured, in pain etc and increases stress and burnout. Increasing the number of techs increases my stress and workload in a different way. I work very hard to stay focused so as not to make a mistake, but it is exhausting to keep track of everything going on. And yet I wouldn't be able to fill all those prescriptions without them. Which means we need another pharmacist if we need more technicians. And with staffing where it is, we are almost always "behind."
194	We have a central fill location which is supposed to help us with workload but it cause many problems which includes customer complaints. It also automatically pull in non maintenance medications such as Ibuprofen and other medications and when the customers come in to pick up their medication, we have to pull it back and it takes extra time which could have been avoided
195	We need more breaks or lunch should be longer than 30 minutes
196	We need more specializes pharmacy and pharmacist to offer a better service. We are trying to do to much at one setting
197	While my current employer is not as bad, I had to quit my previous employer Walgreens due to such stressful job environment, more goals/quotas to be met, pressure from store managers and district managers who some dont event have pharmacist degree but di
198	Without enough staffs to accommodate work flow and patient care, there is higher chance to make errors because everyone has to work faster and harder to meet metrics. Besides that limited staff also affected the time patient has to wait in pharmacy to pick up their medications.
199	working less hours per week is the key for my life change
200	Yes, pharmacy is a business but also a means for patients to get life saving medication. This should be taken seriously. Pharmacists should be able to safely evaluate each prescription and not push for completion due to time constraints from the company and deal with constant interruptions that open the door for numerous medication errors.
201	You cannot tell me that a pharmacist being pulled in 6-12 directions at any one time will never make a mistake. You cannot tell me that a technician trying to multitask at the same level wont make a mistake. My company likes to say that some techs act
202	No response.

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1	**Question 57: Please share any other comments you may have:**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **a. Institutional/Hospital Pharmacy**
3	**Responses**
4	Allergies!!!
5	Allow pharmacists to make clinical judgements regarding medications. (Ie; 2 lisinopril 2.5mg daily instead of one 5mg tablet
6	Before our current management took over, we had amazing outcomes with our diabetic patients and hypertension patients because we had in person visits with them, the pandemic changed that to telephone visits, which are often no show and not effective. We need to go back to being 50% clinical & 50% retail like we were; this will greatly improve patient safety & outcomes, in addition to eliminating errors. We also need to be less cluttered; our manager focuses on ordering things and overfilling the pharmacy, rather than anything to do with patients; he does not care about the patients at all, sadly. We need a major refocus in our management, but this has been a struggle, he distracts more than he ever helps, unfortunately.
7	better understanding of pharmacist work from physicians and Nurses. Also from general public.
8	[redacted] is a patient safety nightmare. Please do something about it!!! Staff is scared to work here and management doesnt care
9	Dea caps on scheduled rxs dispensed without the pharmacy knowing what that cap is does not help with the opioid crisis but instead compromise patient safety for those in need of these medications for legitimate reasons
10	Even though more tech would be helpful to get things done, if the ratio is too great, it is hard to check everything safely (without rushing which could lead to more errors).
11	Hospital pharmacy is 200% less stressful than retail pharmacy. Workload is about half with more staff.
12	Hospital setting is very different than retain setting for patient safety, but the priority is still number 1.
13	I do other projects for the company I work for outside of pharmacy hours, that can be stressful, but the pharmacy work during business hours is easily accomplished. My biggest stress is the computers going down.
14	I know retail pharmacies are massively overwhelmed, especially during vaccination times. But I wish that the board of pharmacy paid better attention to hospital pharmacies. We are also massively understaffed in Nevada and we are also looking into unionizing.
15	I only work part time currently due to a past pharmacy job of high stress, high workload, and spending 60 hrs a week working, when only being compensated for a 40 hour week. Basically I burnt out
16	I quit retail about 2 years ago. The big companies will never come with more help unless forced. Its as bad as youve heard.
17	I realize that the healthcare system is struggling, in my setting the administration is so far out of touch with the daily needs and struggles of our department ~ we are unseen and unrecognized.
18	I switched careers from [redacted] to [redacted] pharmacy. Both pharmacies processed the same amount of prescriptions, but the biggest difference is that instead of having one pharmacist working an 10+ shift there are sometimes 3-4 pharmacist each working an overlapped 8 hour shift. This allows the pharmacists to spread the amount of consultations, vaccines and other non-dispensing activities amongst themselves. Moreover, the pharmacist is not pressured to spend such little time on prescription verification, but rather can safely analyze DUR and seek clarification without sacrificing on getting patients their medications in timely manner. My work life balance has been greatly increased since making the switch.
19	I want to love where I work, but some days it worries me to be there when I see how little administration cares about us and in turn how little they actually care for patient safety.
20	I would prefer to hire more technicians than less but it could have a positive or negative impact on patient safety and medication errors. Some technicians are not very detail oriented and make a lot of mistakes whereas others are very accurate. Hiring more pharmacists concurrently would help pharmacists spread the workload and not feel overwhelmed with the amount of items to check that techs have prepared. I believe both hiring more pharmacists and more technicians would improve patient safety and reduce med errors
21	It would be so nice to feel like we have a board that cares for us. It feels like it works against us and any time I have called I get an "you're a pharmacist, you should know" attitude.
22	Its not necessarily the number of techs working. Its their work responsibilities that need updated.
23	KEEP IN MIND I WORK IN A HOSPITAL WITH 800+ BEDS ADMITTED ON THE ADULT SIDE. BUT THERE IS ALSO CHILDRENS HOSPITAL AND THE ER PATIENTS TO CONSIDER. ON DAY SHIFT, THERE IS MORE STAFFING, ON SWING SHIFT STAFFING DECREASES, AND ON 3RD SHIFT - WE ARE BARE BONES SKELETON CREW BUT PATIENT VOLUME AND DEMAND DOES NOT CHANGE. AND FREQUENTLY INCREASES.
24	Lots of pharmacists feel they are not supported by their own governing organization and are left to rot. Whereas nursing and physician groups at least try to support their profession. The liabilities of the law, the additional responsibilities, and the ever increasing risk of patient safety that we carry on our broken backs just isn't worth proceeding in this profession anymore. The non-existant pay increases over the past couple of decades does not match up all the additional responsibilities and work we all have to endure.

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25	Many of these questions are not applicable for hospital and clinical pharmacists so consider a separate survey for them to address
26	N/A
27	NA
28	NA.
29	Nevada is also behind other states in what pharmacists are able to do within their scope of practice. Many more states have outpatient/inpatient prescribing, more liberal collective practice agreements, etc. As more of these practices (such as COVID immunizations, Paxlovid prescribing, vancomycin AUC/MIC dosing, etc) have been slowly introduced in Nevada the number of pharmacists staffing has stayed the same. And employers and institutions haven't appeared to show any interest in providing more FTEs for the additional work. This will only get worse as other states expand pharmacists scope of practice. And allowing technicians to do pharmacist duties (such as immunize) under pharmacist supervision just allows employers to not staff more pharmacists but carry more of a liability being responsible for the activities an individual without even a 4-year degree which we have to directly supervise anyway.
30	No other comments
31	None
32	not at this time
33	Over my 30+ years in pharmacy I have seen an increased emphasis on patient safety, so much so that I earned a credentialing in patient safety. However, the emphasis on USP 797 and 800 , though extremely important and does add dimensions of patient safety, has created delays in patient care due to the "extra steps" in creating a sterile/accurate dose. These delays add extra stress to an already busy patient care process.
34	Pharmacy has gone downhill, we let employers push us around to much and for too long.
35	Pharmacy has not been what I imagined it would be¦these companies make sooooo much money off the backs of our hard work. Its very easy and quick to lose motivation (I see sooo many pharmacists and especially techs who do the bare minimum) this means
36	Pharmacy has not really changed and retail always drive for profit and under staffing due to management greed and lack of empathy.
37	PROVIDERS NEED TO BE HELD ACCOUNTABLE - THEY DO NOT ANSWER THE PHONES, THEY ALLOW UNEDUCATED MA'S TO GIVE RX'S OVER THE PHONE, AND GIVE MEDICATIONS WITHOUT A PHARMACIST REVIEW AND NO KNOWLEDGE OF THE PT'S OTHER MEDICATIONS LEADING TO ERRORS
38	Receive meal break required by law , but zero additional breaks
39	Reflecting on my entry into retail pharmacy about 15 years ago, the staffing levels were reasonable, enabling us to manage our workload efficiently. I could dedicate time to addressing issues, conducting follow-ups with healthcare providers, and ensuring comprehensive patient care. With my background in hospital and ambulatory care pharmacy, I comfortably balanced the demands of retail until I transitioned to an ambulatory care role in a hospital. However, during my five years in retail pharmacy, I witnessed concerning changes in the work dynamics. There was a persistent push to reduce technician hours and replace experienced technicians with lower-cost hires and minimal training. This restructuring impacted workflow, forcing unreasonable speed expectations on the remaining staff, leading to psychological and physical burnout for both technicians and pharmacists. The high turnover resulted in constant changes within the team, disrupting continuity and patient care. The working conditions deteriorated to a point where the well-being of healthcare staff was compromised. It became evident that caring for patients necessitates a supportive environment that prioritizes the well-being of the healthcare team. Despite being offered roles of higher responsibility based on performance, I chose not to continue in retail pharmacy due to the discordance between the work environment and my personal values, particularly in the treatment of technicians. I firmly believe that a healthy and supportive work environment is essential for delivering quality patient care, and regrettably, the current conditions in retail pharmacy diverge significantly from these principles
40	some of these questions are difficult to answer related to a hospital clinical pharmacy setting, but sometimes noise levels and interruptions while processing medication orders can be an issue. I've grown accustom to this setting and have personal mental checks to keep myself from putting through orders that I haven't evaluated thoroughly due to distractions/interruptions. I feel like there is very little one can do about it in this setting, unfortunately.
41	Some patient safety issues get swept under the carpet by administration
42	Stop increasing the number of techs per pharmacists. Its more stress on the pharmacists to have to be responsible for them.
43	Survey difficult need more explanation boxes to cover questions things like flex schedule due to census without out reguard to patient aquity
44	Thank you
45	Thank you so much for doing this survey. Timely and important!
46	The increased number of pharmaceutical technicians may pose a threat to patient safety as pharmacists are required to supervise more technician duties
47	Time for patient counseling and developing personal professional relationships.

	A
48	We must put into law minimum staffing for pharmacy size and/or workload - orders processed/dispensed. And not based on quantity of patient.
49	We need more advocates for Pharmacists and patient safety in all types of pharmacy settings
50	No response.

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1	**Question 57: Please share any other comments you may have:**
2	**Question 3: Which of the following most closely describes your primary practice setting?** **c. Independent Pharmacy** **d. Department of Defense or Veterans Affairs Pharmacy** **e. Non-pharmacy practice setting (i.e., a practitioner's office, at home, at a college or university, etc.)** **f. Consultant Pharmacist** **g. None of the above, I am currently unemployed or retired.** **No Response**
3	**Responses**
4	1) I am lucky I can work for a small independent retail store. I would change careers overnight (to my other non-pharmacy part time job which I do work once or twice a month) if I had to work for a chain. They make the pharmacists at the other chain retails in town work 12-13+ hours a day & have to fill over 300 rx's/day. I have filled in on emergency for them & would never do it full time. That is absolutely insane. It is chaos all day. It is horrible for your health. We pharmacists (in general) are treated like fast food restaurant workers flipping burgers all day. I have it easy compared to them and am still burned out. You know how hard it is to get a day off? Nearly impossible. You have to work when you are sick & miserable cause there is no coverage for you. No other profession in the USA abuses their employees like pharmacists are abused. And if I had it to do all over again, I would NOT become a pharmacist. 2) we need to start training employers & pharmacists that in the name of patient safety, only those who truly need their prescription filled right this second (mother with sick kid in her arms) gets special treatment. All other customers need to wait their turn in line & we will get to later in the day. If we would start training everyone that this is a major way to reduce chaos (& the subsequent med errors) life would be better. I have started doing that at my pharmacy & the med errors have dropped dramatically. I repeat dramatically. Catering to every patient right here right now does nothing but create chaos & med errors. Patients are not entitled to have everyone stop what they are doing & fill their rx right now. But that is how it is in a lot of pharmacies & that is the attitude of a lot of patients. That is a disservice to everyone, all in the name creating a competitive edge is getting your script volume up so you can make someone else rich. Again. What ever happened to patient care. Lastly, I am grateful in that I don't have to administer vaccines & all that other non-prescription related stuff otherwise I would leave even this job. Listen, we are tied to preparing a product (prescriptions) for sale to a customer. Until that non-sense is no longer our job, all that other stuff they tout as patient care is just window dressing & has no business detracting from the safe & accurate filling of prescriptions.
5	As mentioned above, with the shifting of more workload to the techs, their pay scale should have been elevated more than it has 16 to 20 bucks an hour is in line with fast food , and the last time I checked, we were healthcare ¦ does that mean anything
6	Being professional in a community pharmacy: requires looking, acting, & speaking professionally. Being ready to work and on time when starting a shift. Help other staff members to perform their best and always remember you will never be appreciated by everyone you serve, since many in our current culture resent anyone standing between them and their drugs.
7	Does the patient truly benefit from a corporate mentality that is driven by œnot how but how many? Why is quality sacrificed for the mere sake of productivity?
8	Don't have one at the moment
9	excessive DEA policy against opiates to the extent patients with severe pain are being grossly under treated for fear of the DEA
10	Hopefully in the future - one day: Dramatically decrease dispensing functions of a pharmacist (which probably will be taken over by AI) and emphasize clinical knowledge/ patient consultation and education regarding patient lifestyle changes, nutrition, and possible drug- drug adverse interactions as well as patient discussions utilizing complementary medicine and assist in the development of an integrative health care approach.
11	I am glad this Problem is finally making an impression on the board as they have always preached patient and public safety while neglecting and not supporting pharmacists who are clearly overwhelmed and have asked for their help.
12	I am so grateful our BOP cares enough about patient safety to send this survey. It gives me hope for our pharmacy profession in Nevada.
13	I answered question 58,59, 60, and 61 based on my experience at a retail pharmacy
14	I feel for the community pharmacists who were being abused by the large chains and denied technician help, all in the quest for decreased cost and increased profit. There has to be a way to balance profit with patient safety, and unsafe working conditions is not it. I feel lucky to have escaped that career choice for much of my career, although poorly-managed hospital pharmacies aren't a picnic either. Gone are the days of employer-employee loyalty and fidelity. I'm glad to have landed a job in IT after 37 years as a clerk, tech, intern and pharmacist in various settings.
15	i hope the board will pass some regulations
16	I left retail pharmacy 10 years ago due to the expectations at that time and they have only gotten worse. I believe errors are frequently not caught because patients don't know to ask questions.
17	I left retail the day I was physically and verbally threatened by a patient and will never work in retail again. The company I worked for had such a poor response.

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18	I left retail this year after COVID pandemic due to increased pressures for providing vaccinations with no additional support in pharmacy staffing, training, roll-out of vaccination preparedness and then after providing over 5,000 shots in a year, having overlap pharmacists hours cut, technician hours cut, increased demands on non-dispensing patient services and metrics. I no longer felt safe dispensing medications for patient care.
19	I left Walgreens when I was sure that I was going to injure a patient or have a stroke due to the amount of hours I worked off the clock. I am certain that the majority of pharmacists who work at Walgreens and CVS now feel the same way. 58 thru 61 were all yes when I worked chain, and all somewhat when I worked at a grocery store.
20	I love being an Infectious Disease Consultant Pharmacist and Consultant Pharmacist
21	I love my current full time position, but do not see myself ever returning full time to a retail setting due to severe staffing shortages and performance metrics.
22	I support removing any metrics for retail pharmacists.
23	I wish that I did not pick "not applicable" because I am retired. If I were to answer these questions, I would answer them as negative responses. All the places that I have worked, the Chief was more concerned about a bonus than patient care.
24	I wish you had sent this survey out a year ago. My current employer is an independent pharmacy and it is amazing. My previous employer was the 3 letter. I worked for them from the time they took over Target pharmacy in 2016 until I quit in August 2022. From the moment [redacted] became my employer, I always told myself I would stop working for them once I felt like conditions were unsafe. I think I stayed a few years longer than that. Even before the pandemic hit, they were reducing technician hours to unsafe levels/stressful levels. Every single day I was scheduled to work I went in one hour before open just to try and set the pharmacy up for success (try to clear out QT, fridge temps, make sure the computers were up and running for the day, etc) and then many days I'd stay late just to clean thing up (put away the order, clear out QP that was overdue, file hard copies, etc) I know I diminished my value as a pharmacist by working off the clock but even with an experienced pharmacy team we could not physically handle taking care of patients and a business with the amount of help they said we were allotted. The quotas they expected were ridiculous - I remember one year [redacted] gave us a flu shot quota of around 1200. Well we reached that goal around late October so they gave us an "extended goal" - nothing was ever good enough for them. The real craziness started when the covid vaccine became available and we were expected to vaccinate all day long while continuing to dispense prescriptions. Sure, they made some technological upgrades which helped make some things faster. However, when you have a diabetic patient being counseled on how to use supplies for the first time and you want to spend 20 minutes helping them out by giving them that human connection you can't because you have vaccine appointments and a million other things to do. It's disheartening. If you really want to see some interesting things you should get your hands on the colleague survey [redacted] gives their employees every year. I'm sure I'm not the only one that begged for more help every year. I became a pharmacist to help people. By the time I finished with [redacted] in 2022, I felt like the only one I was helping was [redacted] to pad their bottom line. They didn't care about their team or their patients. I was just a number making them X amount of profit.
25	I work at an independent pharmacy with other pharmacists. I feel bad for RPhs who work at chains burdened with a lot of work.
26	I worked 14 years in one retail pharmacy and I quit because they cant find relief pharmacist so I can go on vacation (staffing problems)
27	Ive worked at [redacted] and have felt that I didnt have enough help to fill prescriptions safely. Didnt have enough help to be able to take a break, also couldnt get a break to pump while lactating. [redacted] burnt me out and affected my physical
28	If you increase the tech ratio, you are only worsening the problem. All that work is still falling on the ONE pharmacist. That ONE pharmacist will be the bottle neck and will feel pressured to finish all the tasks as quickly as possible. Someone WILL mak
29	Increasing Pharmacy tech ratio will lead to better patient care and safety. By having more techs they will reduce the busy work a pharmacist is doing allowing RPh to do only Rph duties. Final verification and counseling. Increasing or Eliminating the ratio has been shown to work in other states. Every Pharmacist have different abilities those abilities limit how many they can do safely on a individual basis there should be no quota for what they must get done.
30	Most of these questions do not represent my current conditions. We compound. I feel the survey should include an œother option with space for comment.
31	My pharmacy collaborates with nursing and we also have "on call" hours outside of our regularly scheduled shifts.
32	N/A
33	N-a
34	no comment
35	No comments
36	no suggestion
37	None

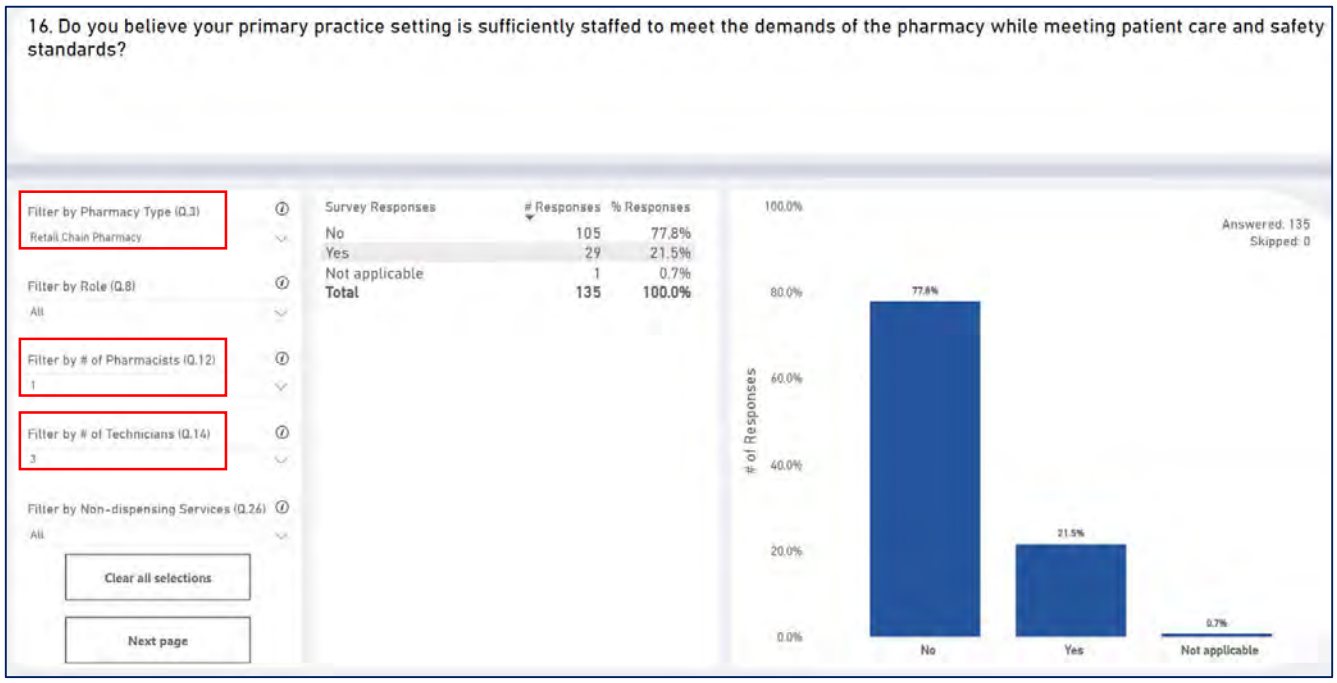
	A
38	Pharmacist and pharmacy personnel have got be more valued by the community, prescribers, and business. Patients of all classes, health status, and financial wellness will wait hours/months if necessary for a doctor appointment but cannot be bothered to wait 5 minutes for their medications???? The pharmacy world is broken by greed of money and time. All medical services were given a great and mighty disservice when they became a business and not healthcare. My position with DHA/DOD is much better that it was in RETAIL, but there is still room for much improvement. My job in retail and here has been reduced to be an editor of my technicians, the doctors, and even the patients. I feel my degree as a pharmacist is being only about 10% of the time, yet I am still paying for a $200,000 education that brings me very little reward other than a pay check.
39	Pharmacy cannot be treated like a fast food situation although some of those business have implemented strong quality check measures to ensure accuracy.
40	Q47. Remove eliminate and use decrease to describe the factors distracting RPh when processing orders in community & hospital RX
41	see the above comments. We need to have more pharmacist to assist our patients. Do NOT increase technician ratio's. A pharmacist cannot have a high metrics, flu shots, patient questions, increase technician & cashier ratio; increase phone calls, consults to better serve our patients. There is a mass exodus of people leaving the pharmacy career.. There is definitely no work and home life balance. We can't say anything because pharmacist are trying to pay off the loans we have incurred to enter this career. Take a survey: not many pharmacist are happy with their career choices.
42	since the vast majority of errors occur at input, this is where the pharmacist should be, not a tech
43	The practice of pharmacy in a chain retail setting is becoming too stressful and leads to a case of burnout for the Pharmacist
44	There is a limit to what one pharmacist, even with competent PharmTech help, can reasonably safely process. That limit can change from day to day or even hour to hour based on multiple factors: health of pharmacist or PharmTech that day, unique prescription problems, temperature in the pharmacy, pressure from waiting patients and the looming workload metrics. Most times, you can only complete what you can get done and if that completion rate leaves unfilled prescriptions, then the next day starts off behind. I have a limit and a safe speed and that speed varies based on some of the above items and the competency of the PharmTechs working with me.
45	There is no shortage of Pharmacists but rather, there is a shortage of good paying pharmacist jobs and also a high shortage of conducive work environment.
46	This is an independent pharmacy whos main emphasis is quality service to our patients. We have a small staff that all work well together to provide a good service to our patients. More important than quantity of staff is the quality of staff.
47	TOO MANY TECHNICIANS FOR TOO FEW PHARMACISTS.
48	Unreasonable metric standards should be discontinued , need more pharmacists to do multiple jobs
49	Vaccinations and mtm have no place in a pharmacy setting. Too distracting. Too many interruptions. Main reason I quit practicing pharmacy. These could be addressed by a separate pharmacist, whose job was to vaccinate or do mtms
50	Vaccinations should not be forced requirement of employment especially Covid boosters that are dangerous. Give RPh discretion to give or not give vaccinations. COVID boosters are dangerous and this is documented.
51	Walgreens metrics are a Pt. Safety risk
52	When I was with CVS (2017-2019), I was so run-down and burned out I almost decided to go BACK to school for a non-healthcare related career. I was depressed. I didn't love pharmacy like I used to. I'm so happy I was able to find a different employer and brought my love for pharmacy back to life.
53	No response.

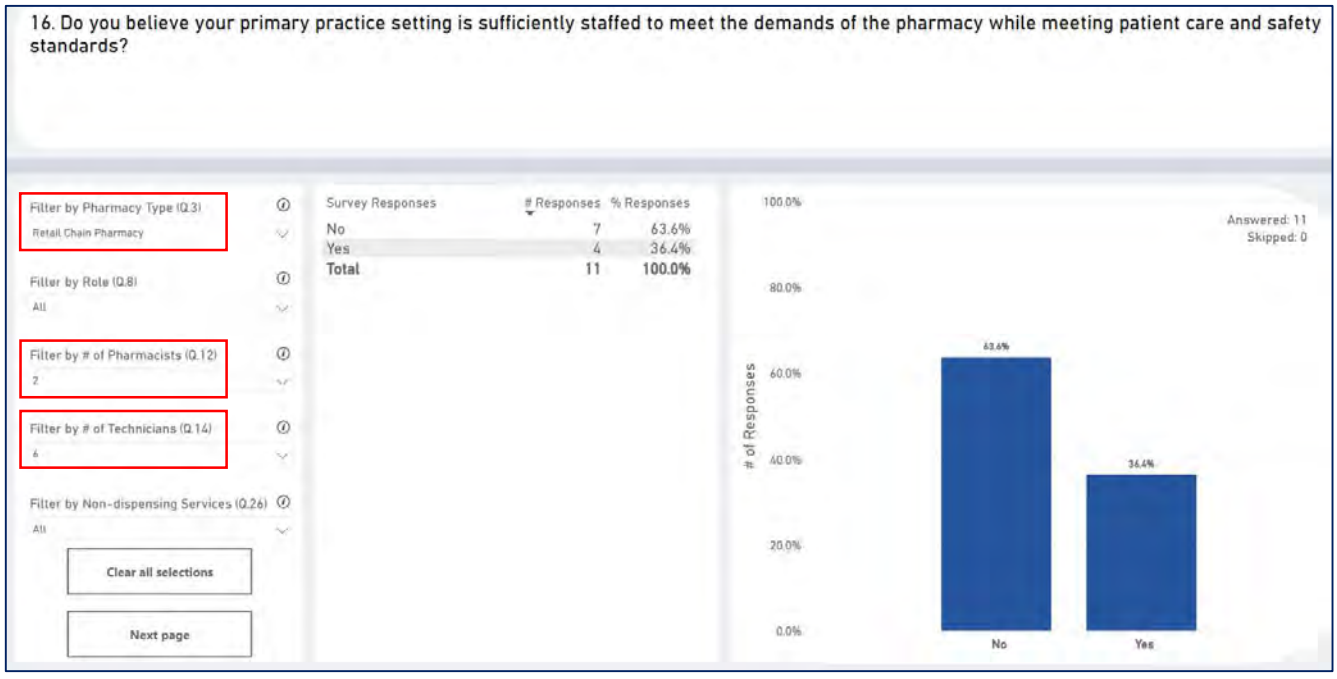


Additional Reports

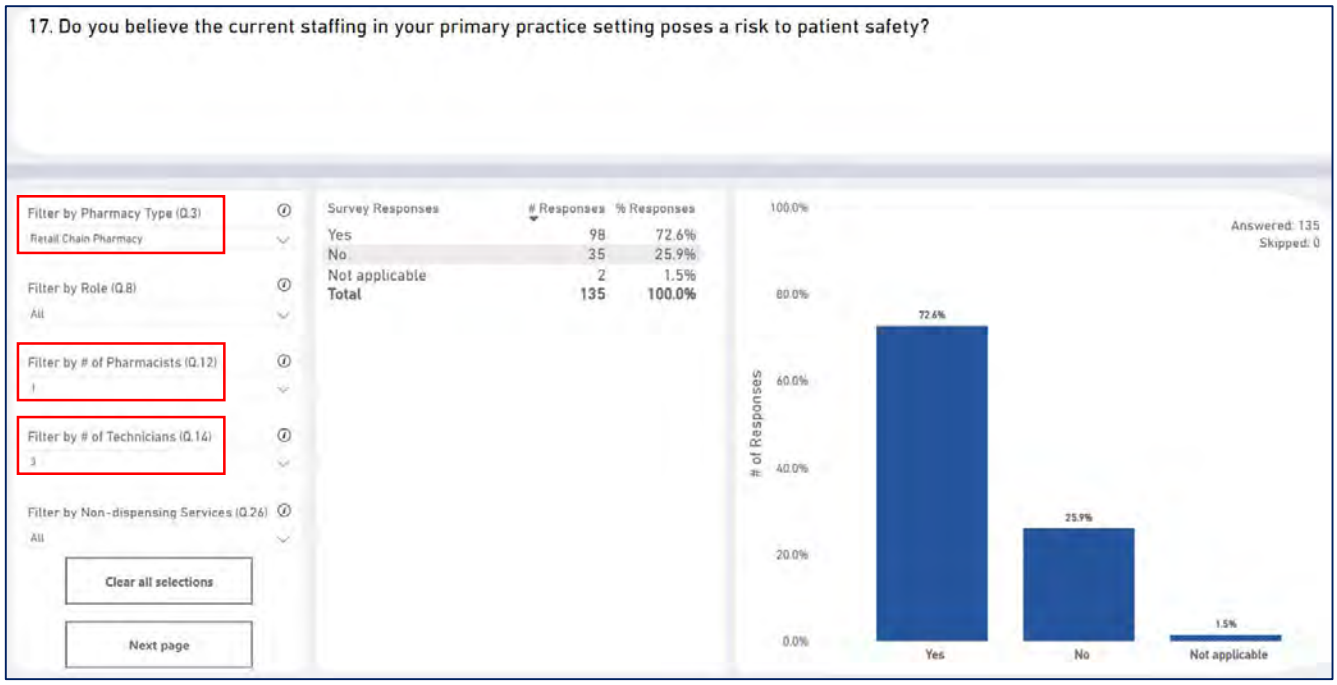
Report 1

This report provides a view to certain survey questions depending on the staffing model in a Retail Chain Pharmacy setting. This report specifically looks at the responses to questions 16, 17, 18 and 47 based on Retain Chain Pharmacies staffed with one (1) pharmacist and three (3) pharmaceutical technicians vs two (2) pharmacists and six (6) pharmaceutical technicians. (As a reminder, the results of **question 12** demonstrated that most Retail Chain Pharmacies staff their pharmacy with one (1) pharmacist per shift (67.2% of responses) or two (2) pharmacists per shift (21.5% of responses) and the results of **question 14** demonstrated that most Retail Chain Pharmacies staff their pharmacy with three (3) pharmaceutical technicians per shift.)

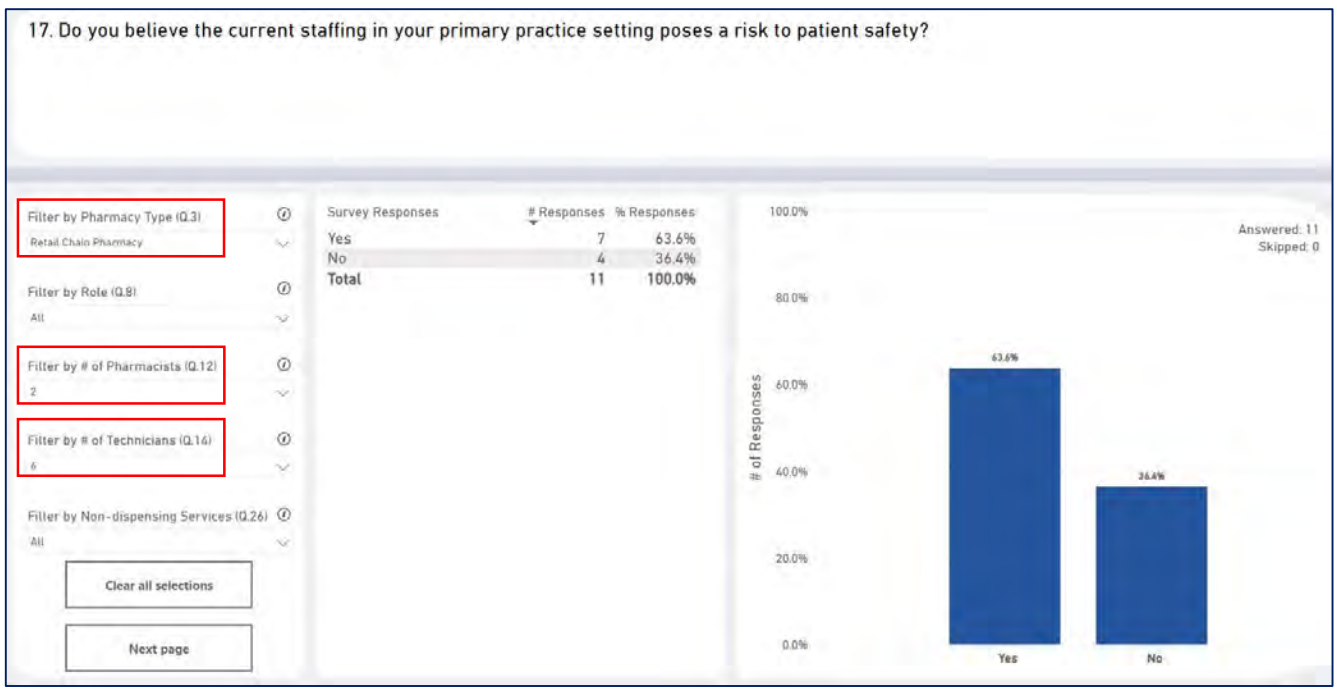




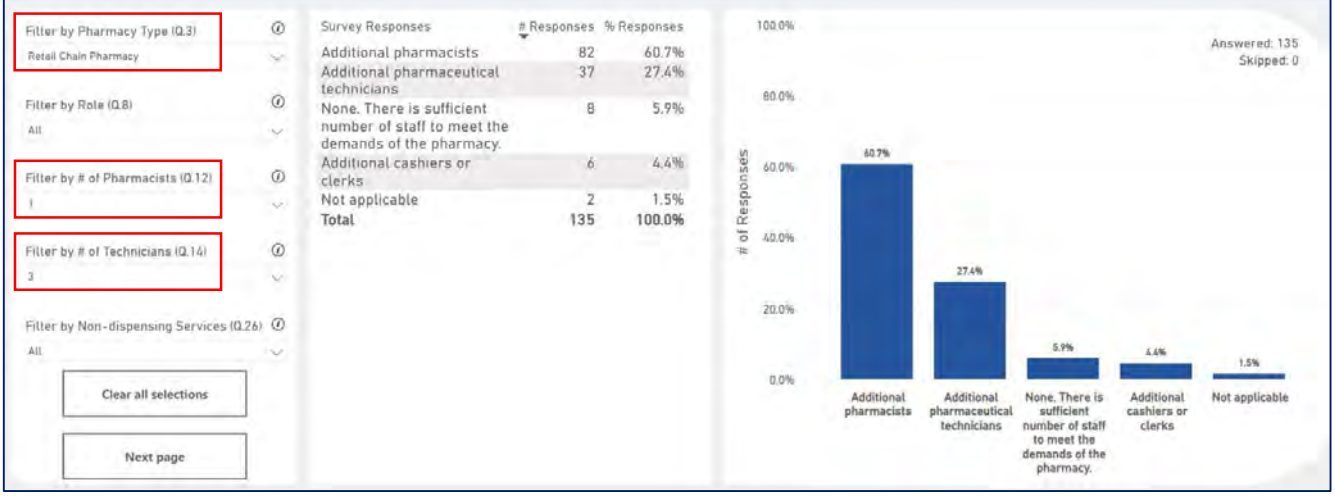
17. Do you believe the current staffing in your primary practice setting poses a risk to patient safety?



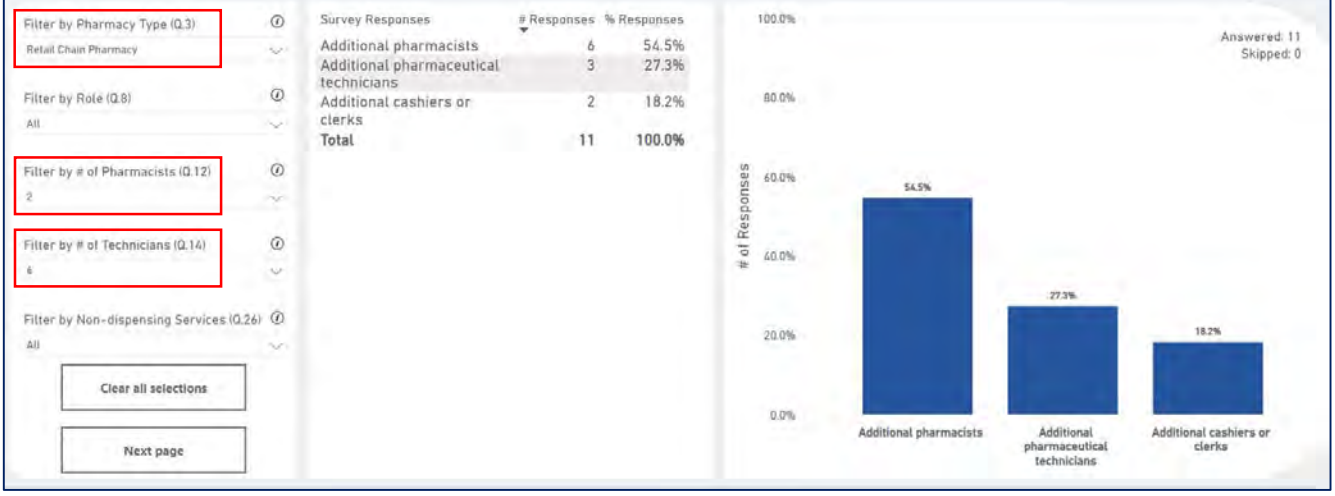
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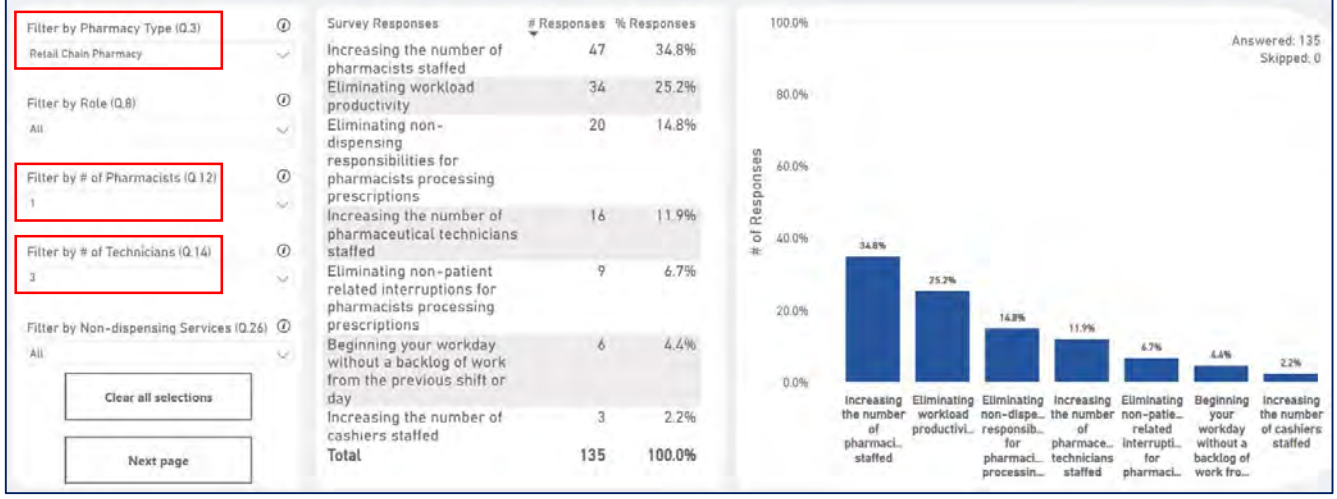
18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?



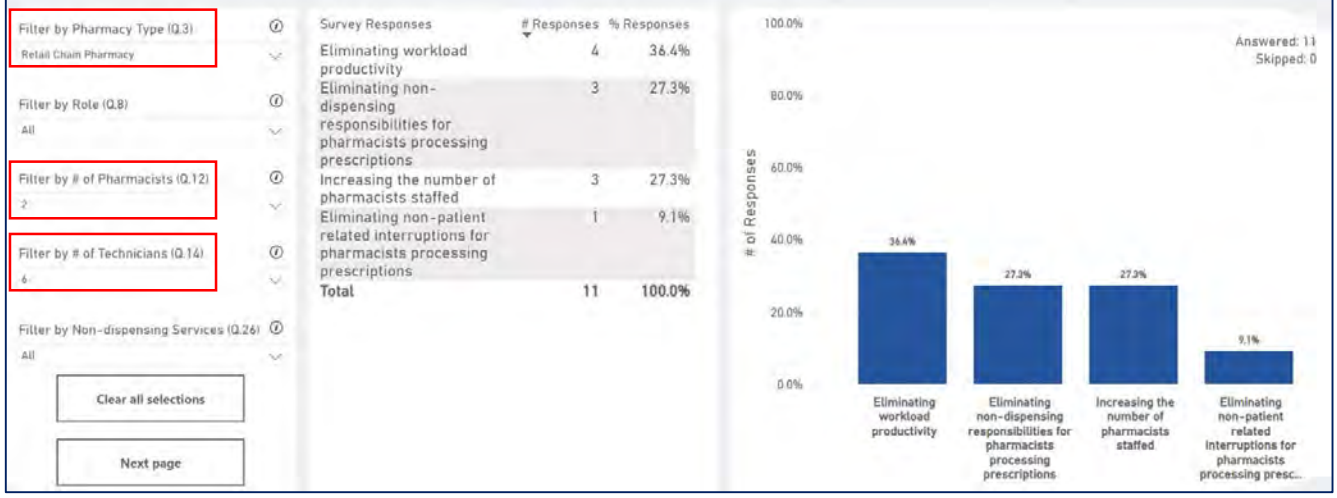
18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?



47.1 The reponses below were ranked as 1 (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety).

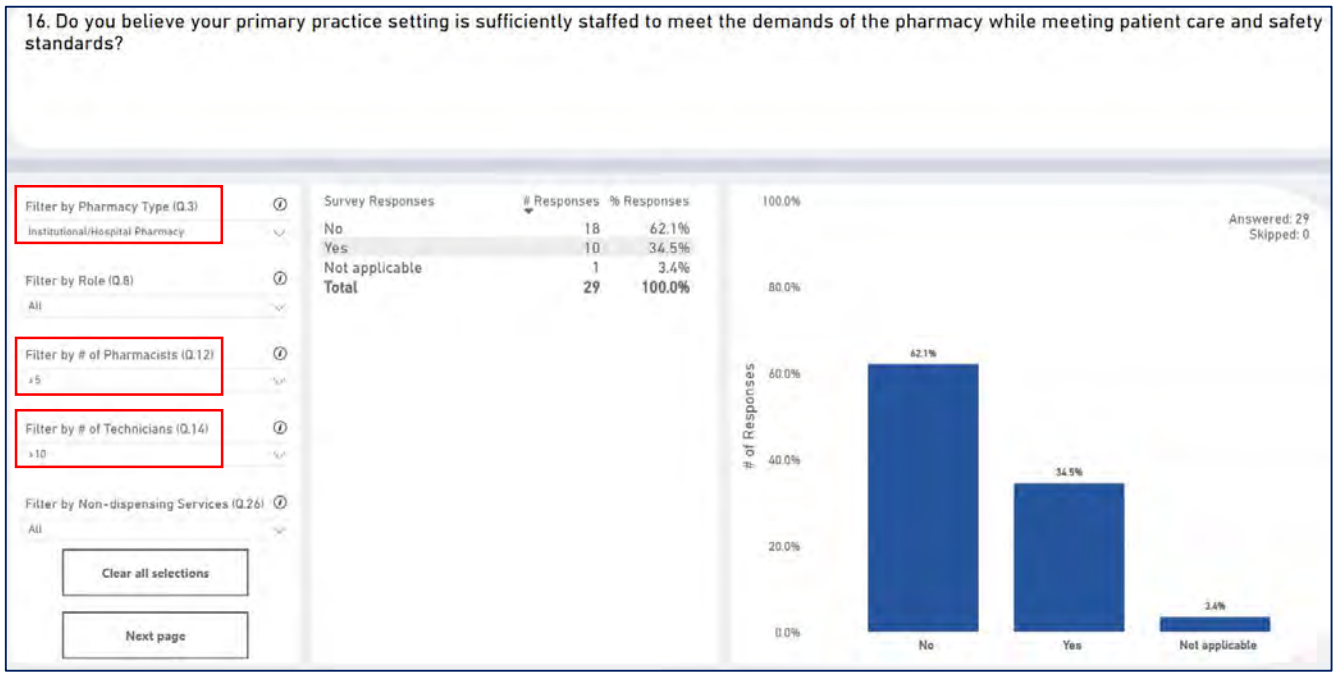


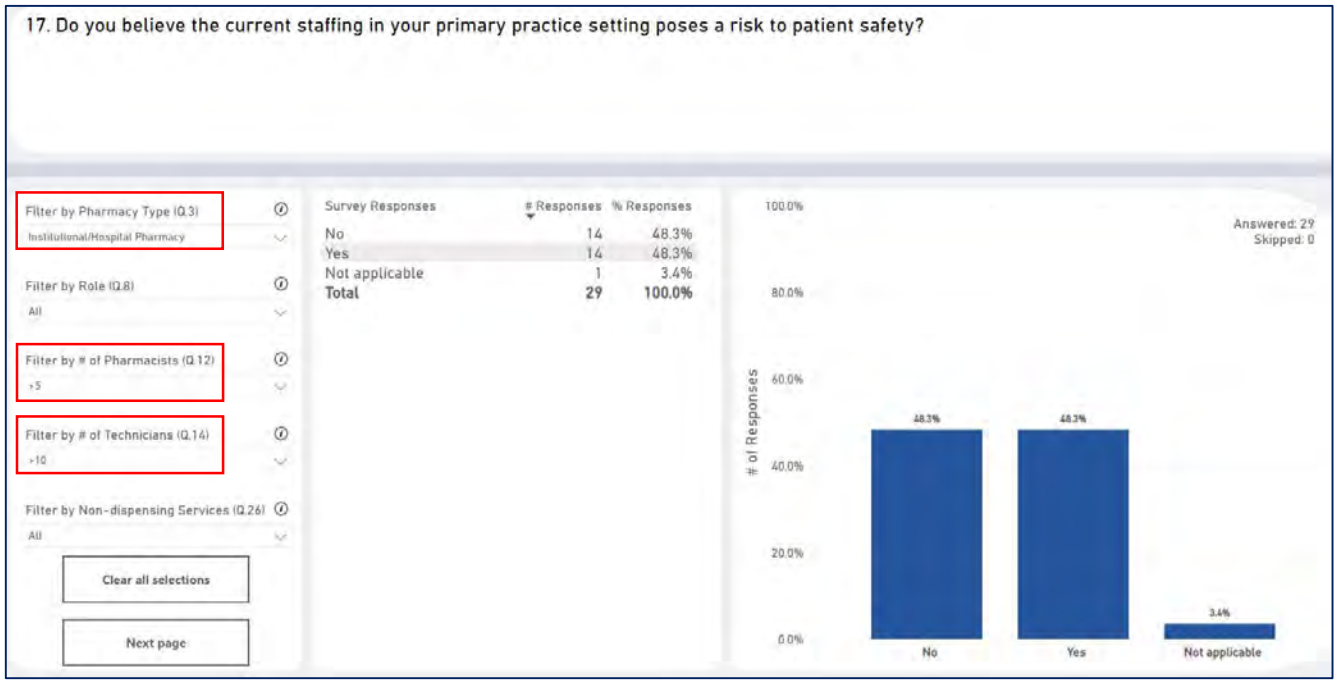
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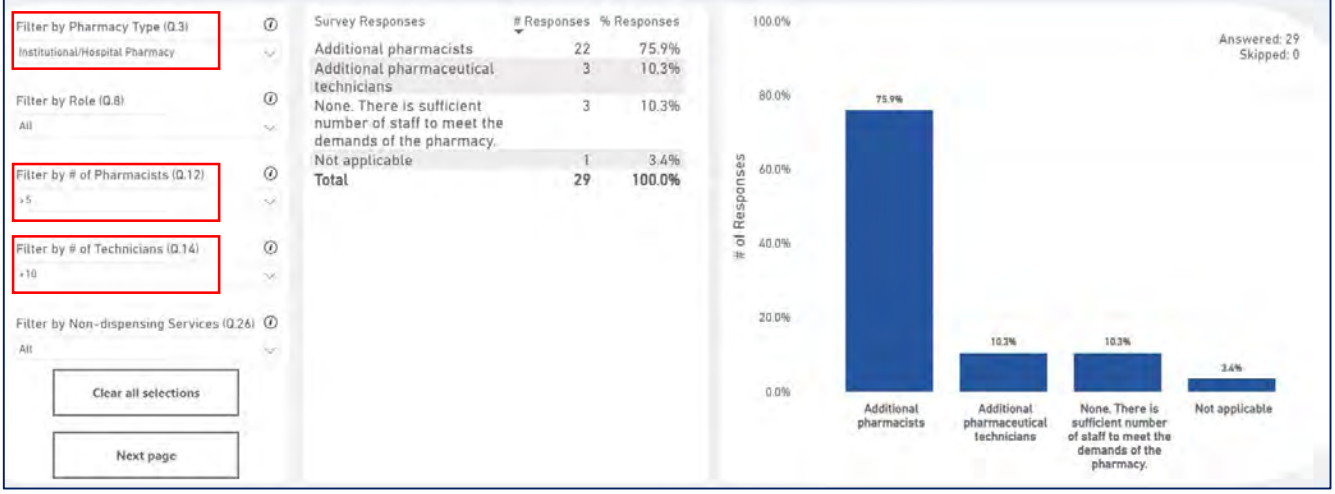
Report 2

This report provides a view to certain survey questions depending on the staffing model in an Institutional/Hospital Pharmacy setting. This report specifically looks at the responses to questions 16, 17, 18 and 47 based on Institutional/Hospital Pharmacies staffed with greater than five (5) pharmacists and greater than ten (10) pharmaceutical technicians. (As a reminder, the results of **question 12** demonstrated that most Institutional/Hospital Pharmacies staff their pharmacy with greater than five (5) pharmacists per shift (36.7% of responses) and the results of **question 14** demonstrated that most Institutional/Hospital Pharmacies staff their pharmacy with greater than ten (10) pharmaceutical technicians per shift.)

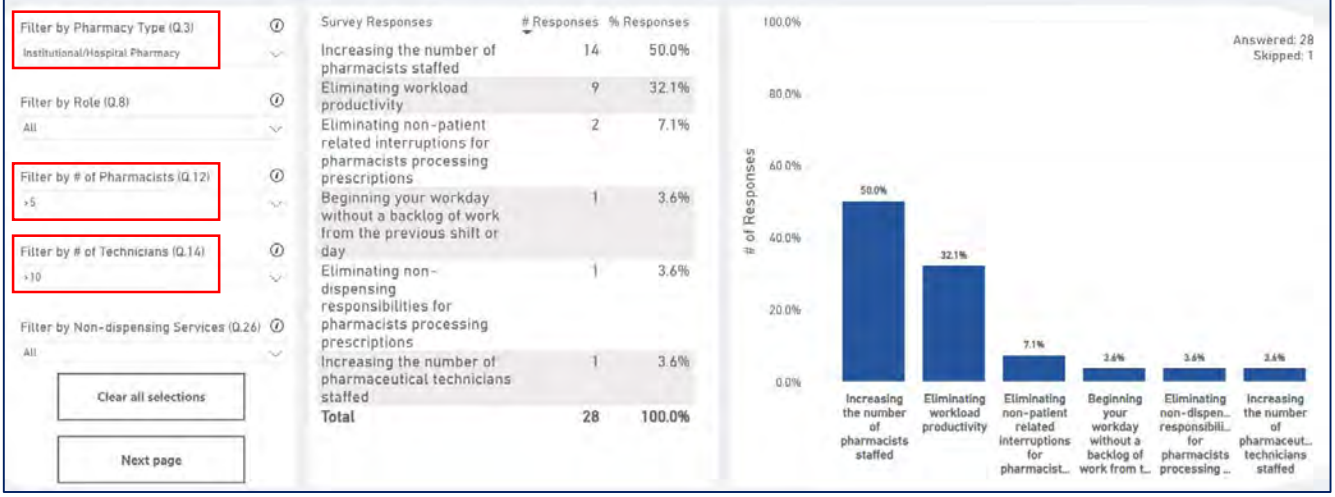




18. If you could choose to add more staff to assist in the demands of the pharmacy to ensure patient care and safety is prioritized, which would you choose?



47.1 The reponses below were ranked as 1 (1 having the most positive impact on patient safety and 7 having the least positive impact on patient safety).



17

18

Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Licensing Update

January 2025 Temporary License since last Board Meeting

Name	License Type
Martha Oppong	Pharmacist
Deidra Lorio	Pharmacist
Antoinette McDonald	Pharmacist
Chancellor Charette	Pharmacist
Alexis Dolin-Stevens	Pharmacist

January 2025 – Out-of-State Business Temporary Licenses Only

Application Status	Business Name	License Number	Location	City, State
New	Advanz Pharma (US) Corp.	WH03750	2801 Lakeside Dr Ste 210 Office 7	Bannockburn, IL
New	Saveway Compounding Pharmacy LLC	PH04656	31 Albe Drive	Newark, DE
New	AmeriPharma MedBox	PH04658	23041 Avenida De La Carlote, Ste 310	Laguna Hills, CA
New	Coloplast Corp.	WH03724	680 E Travelers Trail	Burnsville, MN

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 – sent revised version to Dave/Yenh	12/10/24	1/16/25		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24					

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24					
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24; Waiting for the federal reg to pass. Then, the Board would like to see at a future meeting.							

A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24					

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 1**
  - **Other: 0**
- **Citation & Fine –**
  - **Unlicensed Practice: 0**
  - **Misfill: 0**
  - **Other: 3**

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